

Epiduo® Gel and Epiduo Forte® Gel eLearning System

Welcome to the Epiduo and Epiduo Forte Module

The screenshot displays the main menu of the eLearning system. At the top center, the title "Epiduo and Epiduo Forte" is prominently shown in red. In the top right corner, the "iDASH" logo is visible. Below the title, there are six numbered options arranged in two rows of three:

- 1 Epiduo Gel Overview**: Features a portrait of a male doctor.
- 2 Annotated Epiduo Gel Prescribing Information**: Features a diagram of skin layers with a pen pointing to specific areas.
- 3 Clinical Studies**: Features two young children smiling.
- 4 Epiduo Forte Gel Overview and Annotated PI**: Features a portrait of a young woman.
- 5 eFlashcards**: Features a portrait of an older woman.
- 6 Assessment**: Features a pencil writing on a grid with letters and numbers.

At the bottom left is the Galderma logo for "EPIDUO FORTE". In the center, a note reads: "For internal use only. Not to be used or distributed outside of Galderma." At the bottom right is the Galderma logo for "Epiduo".

Narration

Welcome to the Epiduo and Epiduo Forte eLearning System.

This interactive program has been developed to give the Galderma Sales Team background knowledge of Epiduo gel and Epiduo Forte gel, so you are prepared when you engage with health care professionals. You will begin with Lesson 1, which presents an overview of Epiduo gel and its mechanism of action. Lesson 2 focuses on the Epiduo gel Prescribing Information. Then in Lesson 3, we cover the Epiduo gel Pivotal Trials. Finally, Lesson 4 is a summary of the Epiduo Forte gel Prescribing Information.

Before you begin, select the Help button at the top of the screen for instructions on how to navigate the program. When you are ready to start, select Lesson 1 to begin.

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Epiduo® Gel and Epiduo Forte® Gel eLearning System

Is There Something That Can Give Better Results?



LESSON 1 Is There Something That Can Give Better Results? ? A→Z ↓ iDASH

Patients had little to no response to over-the-counter medications

Tried different approaches, with no results

GALDERMA Screen 1 of 5
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Narration

[Physician] My patients with mild acne are usually fairly easy to treat and they seem to respond to several different approaches. What is difficult for me — and I'm sure for other dermatologists — is the patients that do not respond to over-the-counter medications and come into the office or who just doesn't seem to respond as well as I would like. I often have to try one approach, then switch to another one when I see it isn't really working. The most challenging situation is when patients come back to me and ask why the treatment I prescribed isn't working. These are the patients for whom the bar is held pretty high — and it is often difficult to reach.

Is there something that can give my patients better results?

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Epiduo® Gel and Epiduo Forte® Gel eLearning System

Lesson One Learning Objectives

≡ LESSON 1 Lesson One Learning Objectives ? A→Z ↓ iDASH

**Discuss the rationale for
Epiduo gel and Epiduo Forte gel
as acne treatments**

**Explain the mechanism
of action of Epiduo gel**

GALDERMA Screen 2 of 5
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Narration

By the end of this lesson you will be able to discuss the rationale for Epiduo gel and Epiduo Forte gel as an acne treatment and explain Epiduo gel's mechanism of action.

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Epiduo Gel and Epiduo Forte Gel

≡ LESSON 1 Epiduo Gel and Epiduo Forte Gel ? A→Z iDASH

Epiduo Gel Dual Action

Adapalene 0.1% + Benzoyl Peroxide 2.5%

Anti-inflammatory Anti-comedogenic/Comedolytic Antibacterial

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Narration

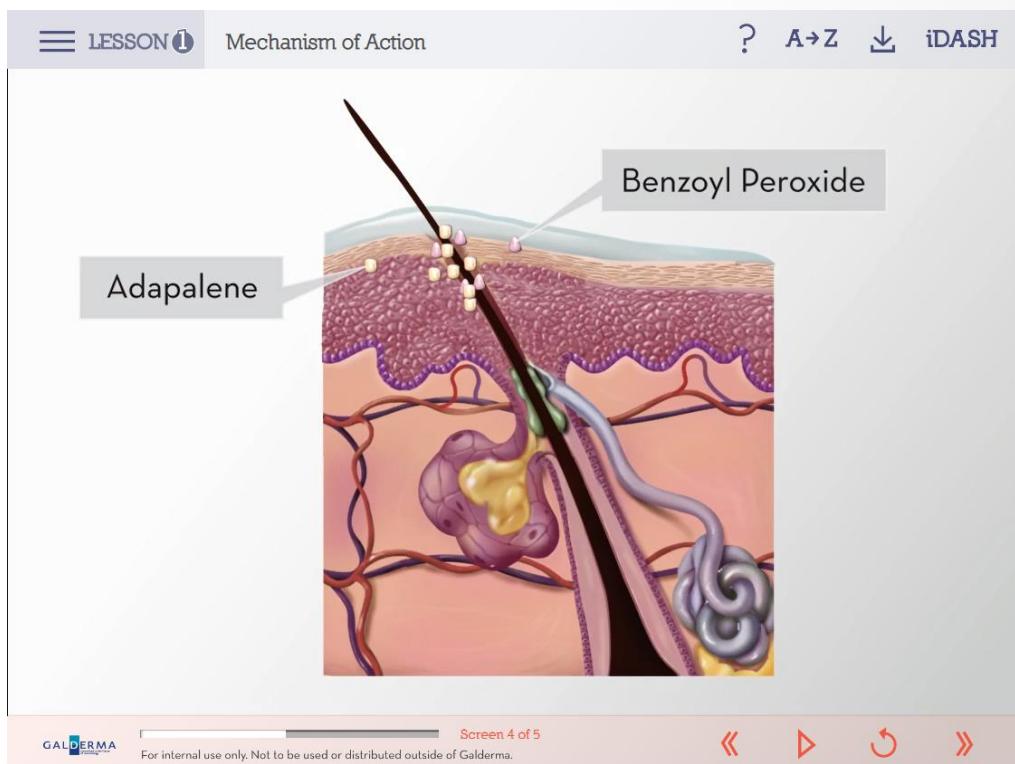
From what you have already learned, you know there is a need for an acne treatment that is effective in a wide range of patients, from those with mild acne to those with more severe acne. Epiduo gel is a dual-action topical gel containing adapalene 0.1% and benzoyl peroxide 2.5%. The first component, adapalene, is a type of retinoid, which can be beneficial for both non-inflammatory and inflammatory acne, and helps prevent the formation of acne lesions. The second component is benzoyl peroxide. It is an antimicrobial, non-antibiotic agent with some anti-inflammatory properties. Because it's an antimicrobial, there are no antibiotic resistance issues. The combination of adapalene and benzoyl peroxide work together to provide fast and long-lasting improvement of acne compared with using either agent separately. Epiduo gel has strong anti-inflammatory, anti-comedogenic, comedolytic, and anti-bacterial components that work against 3 of the 4 causative factors of acne.

The rationale for Epiduo Forte gel was to develop a higher strength product that offers providers another option for acne vulgaris patients with more severe disease. As you will learn later in the module, Epiduo Forte gel demonstrated superior efficacy compared to vehicle in patients with moderate and severe acne.

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Mechanism of Action



Narration

Epiduo gel's exact mechanism of action in treating acne is unknown. However, the rationale behind its effectiveness starts with adapalene and benzoyl peroxide, the 2 main components of Epiduo gel.

Adapalene increases cell turnover in the follicles; this increases differentiation among follicular epithelial cells, thus reducing the opportunity for pores to become plugged and reducing the formation of microcomedones. It normalizes keratinization of the epidermal cells and produces anti-inflammatory action by inhibiting the cell-mediated inflammatory response.

Benzoyl peroxide has antibacterial activity that is particularly effective against *P. acnes*. It is not an antibiotic, and therefore does not induce bacterial resistance. Benzoyl peroxide's antimicrobial activity comes from oxidation, similar to how we disinfect hard surfaces with hydrogen peroxide. Benzoyl peroxide also helps control the excessive sebum production usually associated with acne and exfoliates the skin's top layer, helping decrease clogged pores.

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Global Alliance Treatment Algorithm

LESSON 1 Global Alliance Treatment Algorithm ? A-Z iDASH

Adult Pediatric

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Narration

The Global Alliance to Improve Outcomes in Acne guidelines recommend combination retinoid-based therapy as first line for treatment of acne, with a topical retinoid and antimicrobial agent being the preferred approach.

This combination attacks 3 of the 4 major pathogenic factors of acne: abnormal desquamation, *P. acnes* colonization, and inflammation. Fixed-dose combination products with a topical retinoid and an antimicrobial may also minimize the development of bacterial resistance. The report states that adding an antimicrobial to a topical retinoid therapy significantly improves the treatment of inflammatory acne.

Tap each button to review the guidelines for the treatment of acne for both adult and pediatric patients.

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Adult

≡ LESSON 1 Global Alliance Treatment Algorithm ? A→Z ↓ iDASH

Adult **Pediatric**

 **Mild** **Moderate** **Severe** →

Adult					
	Comedonal	Mixed and Papular/Pustular	Mixed and Papular/Pustular	Nodular	Nodular/ Conglobate
1st Line	Topical Retinoid	Topical Retinoid + Topical Antimicrobial	Oral Antibiotic + Topical Retinoid +/-BPO	Oral Antibiotic + Topical Retinoid + BPO	Oral Isotretinoin
Alternatives	Alt. Topical Retinoid or Azelaic acid or Salicylic acid	Alt. Topical Retinoid Antimicrobial Agent + Alt. Topical Retinoid or Azelaic Acid	Alt. Oral Antibiotic + Alt. Topical Retinoid +/- BPO	Oral Isotretinoin or Alt. Oral Antibiotic + Alt. Topical Retinoid +/- BPO/azelaic Acid	High Dose Oral Antibiotic + Topical Retinoid + BPO
Maintenance	Topical Retinoid		Topical Retinoid +/-BPO		

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Pediatric

LESSON 1 Global Alliance Treatment Algorithm ? A→Z ↓ iDASH

Adult Pediatric

Mild Moderate Severe

Pediatric			
	Comedonal or Inflammatory/Mixed Lesions	Comedonal or Inflammatory/Mixed Lesions	Inflammatory/Mixed and/or Nodular Lesions
Initial Treatment	Benzoyl Peroxide (BP) or Topical Retinoid or Topical Combination Therapy BP + Antibiotic or Retinoid + BP or Retinoid + Antibiotic + BP	Topical Combination Therapy Retinoid + Benzoyl Peroxide (BP) or Retinoid + (BP + Antibiotic) or (Retinoid + Antibiotic) + BP or Oral Antibiotic + Topical Retinoid + BP or Topical Retinoid + Antibiotic + BP	Combination Therapy Oral Antibiotic + Topical Retinoid + Benzoyl Peroxide (BP) +/- Topical Antibiotic
Inadequate Response	Add BP or Retinoid, If Not Already Prescribed or Change Topical Retinoid Concentration, Type and/or Formulation or Change Topical Combination Therapy	Change Topical Retinoid Concentration, Type and/or Formulation and/or Change Topical Combination Therapy and/or Add or Change Oral Antibiotic	Consider Changing Oral Antibiotic AND Consider Oral Isotretinoin

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Lesson 2 Learning Objectives

The screenshot shows a mobile application interface for 'Lesson Two Learning Objectives'. At the top, there's a navigation bar with icons for 'LESSON' (with a number '2'), 'Lesson Two Learning Objectives', a magnifying glass, 'A-Z', a downward arrow, and 'iDASH'. Below the navigation is a large, semi-transparent circular graphic containing the text 'Summarize the key points of the PI for Epiduo gel'. Underneath this, another circular graphic contains the text 'Describe the clinical trial data that is presented in the PI'. At the bottom of the screen is a footer bar with the Galderma logo, a progress bar indicating 'Screen 1 of 12', the text 'For internal use only. Not to be used or distributed outside of Galderma.', and navigation icons: a double-left arrow, a double-right arrow, a circular arrow, and a single-right arrow.

Summarize the key points of the PI for Epiduo gel

Describe the clinical trial data that is presented in the PI

Screen 1 of 12
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Narration

The Prescribing Information, or PI, is a document that accompanies prescription medication and provides information about the medication. When you are in the field, health care providers may want to discuss information in the PI. To prepare you for this kind of conversation, this lesson will review the most important points of the PI for Epiduo gel.

When you have completed this lesson, you should be able to:

- Summarize the key points of the PI for Epiduo gel, and
- Describe the clinical trial data that is presented in the PI.

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Epiduo Gel Prescribing Information

The screenshot shows a mobile application interface for the Epiduo Gel Prescribing Information. At the top, there is a navigation bar with icons for 'LESSON' (with a count of 2), 'Epiduo Gel Prescribing Information', a magnifying glass icon, 'A-Z', a download icon, and 'iDASH'. Below the navigation bar is a horizontal menu with four items: 'Indications' (selected), 'Dosage and Administration', 'Dosage Forms and Strengths', and 'Contraindications'. The main content area displays the 'Indications' section of the prescribing information, which includes sections on 'INDICATIONS AND USAGE', 'DOSE AND ADMINISTRATION', 'DOSE FORMS AND STRENGTHS', and 'CONTRAINDICATIONS'. A detailed description of 'INDICATIONS AND USAGE' is visible, mentioning the treatment of acne vulgaris in patients aged 12 years and older. Below this section is a table titled 'Table 1: Characteristics of Localized Cutaneous Adverse Events Reported in Clinical Trials of Acne Vulgaris Patients Dosed Up to 12 Months' and another table titled 'Table 2: Characteristics of Localized Cutaneous Adverse Events Reported in Clinical Trials of Acne Vulgaris Patients Dosed Up to 12 Months'. At the bottom of the screen, there is a footer with the Galderma logo, the text 'Screen 2 of 12', and the instruction 'For internal use only. Not to be used or distributed outside of Galderma.'

Narration

Let's review some of the key sections of the Epiduo gel PI: Indications, Dosage & Administration, Dosage Forms and Strengths, and Contraindications. Tap each button to review each section of the PI. When finished, tap the forward button to continue.

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Epiduo® Gel and Epiduo Forte® Gel eLearning System

Indications

Narration

Epiduo (adapalene and benzoyl peroxide) gel, 0.1%/2.5% is indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.

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Epiduo® Gel and Epiduo Forte® Gel eLearning System

Dosage and Administration

LESSON 2

Epiduo Gel Prescribing Information

? A[→]Z iDASH

Indications

Dosage and Administration

Dosage Forms and Strengths

Contraindications

2 DOSAGE AND ADMINISTRATION

For topical use only; EPIDUO gel is not for oral, ophthalmic, or intravaginal use.

Apply a thin film of EPIDUO gel to affected areas of the face and/or trunk once daily after washing. Use a pea-sized amount for each area of the face (e.g., forehead, chin, each cheek). Avoid the eyes, lips and mucous membranes.

Reference ID: 032045

Screen 2 of 12

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Narration

Epiduo gel is for topical use only. Epiduo gel is not for oral, ophthalmic, or intravaginal use and should be applied once daily to affected areas of the face and/or trunk after washing.

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Dosage Forms and Strengths

The screenshot shows a digital interface for 'Epiduo Gel Prescribing Information'. At the top, there's a navigation bar with 'LESSON 2' and a question mark icon. Below the navigation bar are four tabs: 'Indications', 'Dosage and Administration', 'Dosage Forms and Strengths' (which is highlighted in red), and 'Contraindications'. The main content area displays a detailed document titled 'FULL PRESCRIBING INFORMATION'. This document includes sections such as 'INDICATIONS AND USAGE', 'DOSE AND ADMINISTRATION', 'ADVERSE REACTIONS', and 'CONTRAINDICATIONS'. It also contains tables for 'Table 1: Once Daily Adapalene/Benzoyl Peroxide Gel 0.1% / 2.5% Gel Dosage Forms and Strengths' and 'Table 2: Number of Days of Treatment Required to Eradicate Acne Vulgaris'. At the bottom of the page, there's a note: 'For internal use only. Not to be used or distributed outside of Galderma.' A 'Reference ID: 2020546' is also present. The bottom right corner features navigation icons: a left arrow, a double left arrow, a double right arrow, and a right arrow.

Narration

Each gram of Epiduo gel contains 1 mg (0.1%) adapalene and 25 mg (2.5%) benzoyl peroxide in a white to very pale yellow, opaque gel.

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Contraindications

Narration

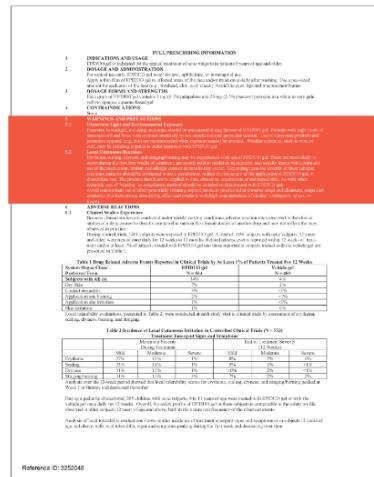
There are no contraindications to Epiduo gel.

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Warnings and Precautions

≡ LESSON 2 Warnings and Precautions ? A→Z ⌂ iDASH



5 WARNINGS AND PRECAUTIONS

5.1 Ultraviolet Light and Environmental Exposure

Exposure to sunlight, including sunlamps, should be minimized during the use of EPIDUO gel. Patients with high levels of sun exposure and those with inherent sensitivity to sun should exercise particular caution. Use of sunscreen products and protective apparel, (e.g., hat) are recommended when exposure cannot be avoided. Weather extremes, such as wind or cold, may be irritating to patients under treatment with EPIDUO gel.

5.2 Local Cutaneous Reactions

Erythema, scaling, dryness, and stinging/burning may be experienced with use of EPIDUO gel. These are most likely to occur during the first four weeks of treatment, are mostly mild to moderate in intensity, and usually lessen with continued use of the medication. Irritant and allergic contact dermatitis may occur. Depending upon the severity of these adverse reactions, patients should be instructed to use a moisturizer, reduce the frequency of the application of EPIDUO gel, or discontinue use. The product should not be applied to cuts, abrasions, eczematous or sunburned skin. As with other retinoids, use of "waxing" as a depilatory method should be avoided on skin treated with EPIDUO gel. Avoid **concomitant** use of other potentially irritating topical products (medicated or abrasive soaps and cleansers, soaps and cosmetics that have strong skin-drying effect and products with high concentrations of alcohol, astringents, spices, or limes).

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Narration

Warnings and Precautions include **exposure to ultraviolet light and environmental sunlight exposure**, potential for local cutaneous reactions including erythema, scaling, dryness, and stinging/burning. The product should **not** be applied to cuts, abrasions, eczematous, or sunburned skin, and **hair removal by waxing** should be avoided. **Concomitant** use of other potentially irritating topical products should be avoided.

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Epiduo® Gel and Epiduo Forte® Gel eLearning System

Adverse Reactions

LESSON 2 Adverse Reactions ? A→Z 🔍 iDASH

Drug-related Adverse Events Reported in Clinical Trials by at Least 1% of Patients Treated for 12 Weeks

System Organ Class/ Preferred Term	Epiduo gel (n = 564)	Vehicle gel (n = 489)
Subjects with AE(s)	14%	4%
Dry Skin	7%	2%
Contact dermatitis	3%	<1%
Application site burning	2%	<1%
Application site irritation	1%	<1%
Skin irritation	1%	0%

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Narration

Drug-related adverse events in at least 1% of patients treated for 12 weeks include dry skin, contact dermatitis, application site burning, application site irritation, and skin irritation.

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Epiduo® Gel and Epiduo Forte® Gel eLearning System

Adverse Reactions

The screenshot shows a user interface for an eLearning system. At the top, there is a navigation bar with icons for a menu, lesson 2, search, A to Z, download, and iDASH. The main content area has a title "Incidence of Local Cutaneous Irritation in Controlled Clinical Trials (N = 553) Treatment-emergent Signs and Symptoms". Below this is a table with data. The table has two main sections: "Maximum Severity During Treatment" and "End of Treatment (12 Weeks)". The first section has columns for Mild, Moderate, and Severe. The second section has columns for Mild, Moderate, and Severe. The table rows represent different symptoms: Erythema, Scaling, Dryness, and Stinging/burning. Each row shows the percentage of patients experiencing each level of severity at both points in time.

	Maximum Severity During Treatment			End of Treatment (12 Weeks)		
	Mild	Moderate	Severe	Mild	Moderate	Severe
Erythema	27%	13%	1%	8%	2%	1%
Scaling	35%	11%	1%	9%	1%	<1%
Dryness	41%	13%	1%	10%	2%	<1%
Stinging/burning	41%	15%	3%	7%	2%	1%

- Tolerability among patients aged 9 to 11 was comparable to that observed in older subjects

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Narration

Local reactions included erythema, scaling, dryness, and stinging/burning.

Note that tolerability among patients aged 9 to 11 was comparable to that observed in older subjects and that local reactions peaked at week 1 of therapy and decreased thereafter.

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Drug Interactions

LESSON 2

Drug Interactions

? A→Z ↴ iDASH

8.2 Promising Emerging Therapies	
The following acne treatments have been identified during preapproval use of EPIDUO Gel, oral isotretinoin, minocycline, or topical clindamycin, resulting in serious, unpredictable adverse reactions, three deaths, and drug withdrawal. These include: (1) severe acne, (2) severe allergic reactions, (3) severe liver damage, and (4) severe eye problems to include cataract and aqueous humor leakage. It is critical to monitor for these reactions.	
8.3 Use in Specific Populations	
Pregnancy Category C: There are no well-controlled studies in pregnant women. Animal studies have shown evidence of teratogenic or fetotoxic potential. There are no adequate studies in pregnant women; however, animal studies are not necessarily predictive of human response. Therefore, EPIDUO Gel should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. No teratogenic effects were observed in rats at doses of 150 mg/kg isotretinoin, 100 mg/kg clindamycin, and 100 mg/kg minocycline. No teratogenic effects were observed in mice and rabbits when treated with doses of 2.5–20 mg/kg isotretinoin, 100 mg/kg clindamycin, and 100 mg/kg minocycline. No teratogenic effects were observed in dogs at doses of 10–100 mg/kg isotretinoin, 100 mg/kg clindamycin, and 100 mg/kg minocycline. Animal studies conducted at low and often at doses of 10-fold the human therapeutic dose did not increase the frequency of birth defects and did not produce a teratogen.	
It is not known whether isotretinoin can passively enter breast milk in amounts of 1% or more of the maternal dose. Because of the potential for serious adverse effects in nursing infants from EPIDUO Gel, it is not recommended to breastfeed during treatment.	
8.4 Pediatric Use	
Safety and effectiveness of EPIDUO gel in pediatric patients under the age of 16 years has not been established.	
It is not known if EPIDUO gel can reduce the incidence number of adverse events and/or to determine whether this reduction in adverse events is greater than the reduction in acne.	
EPIDUO® (isotretinoin and benzoyl peroxide) gel (10.25% w/w) is a white to pale yellow, opaque, gel topical acne medication. Adipex® is a trade name, a registered and exclusive trademark of Adamed Inc. It has the following active ingredients:	
Isotretinoin (1,11-dihydroxy-10-methoxy-9,10-epoxy-4,5-dihydro-5H-cyclohexene-1,2-dione) 10.25% Benzoyl peroxide (2-hydroxy-2-methylpropanoic acid, 4-tert-butyl ester) 10.25%.	
Molecular formula: $C_{20}H_{28}O_4$ Molecular weight: 342.32	
EPIDUO® (isotretinoin and benzoyl peroxide) gel contains two active ingredients: isotretinoin and benzoyl peroxide. Isotretinoin is a tetracyclic derivative of phytol, whereas benzoyl peroxide is a hydroperoxide.	
8.5 Clinical Pharmacology	
Adverse Effects Isotretinoin leads to specific systemic and cutaneous changes that are associated to its toxicity profile. Mechanistic and pharmacological studies have demonstrated that isotretinoin is a modulator of cellular differentiation. Cutaneous adverse effects are mainly related to the toxic effect of this drug being able to disrupt the homeostasis of skin cells.	
Isotretinoin may cause: (1) dryness, (2) irritation, (3) scaling, (4) sensitivity and/or allergic reactions.	
12.2 Pharmacodynamics Pharmacodynamics of EPIDUO gel are unknown.	

7 DRUG INTERACTIONS

Concomitant topical acne therapy should be used with caution because a possible cumulative irritancy effect may occur, especially with the use of peeling, **desquamating**, or abrasive agents.

No formal drug-drug interaction studies were conducted with EPIDUO gel.

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GALDERMA

Narration

This section is about drug interactions and use of Epiduo gel in special populations. Although formal drug-drug interaction studies were not conducted, Epiduo gel should be used with caution with other topical acne therapy to reduce risk of cumulative irritation, particularly if peeling, desquamating, or abrasive agents are applied.

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Use in Specific Populations

≡ LESSON 2 Use in Special Populations ? A→Z ↓ iDASH

Pregnancy 

- **Pregnancy category C**
- Should be used during pregnancy only if potential benefit justifies risk to fetus



Nursing Mothers

Caution should be exercised when administered to a nursing woman



Pediatric Use

Safety and efficacy in pediatric patients under the age of 9 have not been established



Geriatric Use

Unknown whether individuals older than 65 years respond differently from younger subjects



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« || ⏪ ⏩ » Narration

With regard to use in specific populations, Epiduo gel is **pregnancy category C** — no human reproductive studies have been conducted with the combination of agents in Epiduo gel. Epiduo gel should be used during pregnancy only if the potential benefit justifies the risk to the fetus. Caution should be exercised when administered to a nursing woman. The safety and efficacy in pediatric patients under the age of 9 have not been established, and it is unknown whether individuals **older** than 65 years respond differently from younger subjects.

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Mechanism of Action

≡ LESSON 2 Mechanism of Action ? A→Z ↓ iDASH

- Adapalene binds to specific retinoic acid nuclear receptors, but does not bind to **cytosolic** receptor protein

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Narration

Adapalene binds to specific retinoic acid nuclear receptors but does not bind to cytosolic receptor protein.

Biochemical and pharmacological profile studies have demonstrated that it is a modulator of cellular differentiation, keratinization, and inflammatory processes. The package insert states that the significance of these findings with regard to mechanism of action for the treatment of acne is unknown. Benzoyl peroxide is an oxidizing agent with bactericidal and keratolytic effects. It helps to eliminate bacteria and dissolve away keratinized or “hardened” skin.

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Clinical Studies: Overview

The screenshot shows a slide from the eLearning system. At the top, there are navigation icons: three horizontal lines (Lesson 2), a question mark, A-Z, a download arrow, and iDASH. The main content includes a bulleted list of study details and a table of the Investigator's Global Assessment (IGA) scale.

• Epiduo gel evaluated for the treatment of acne vulgaris

• Two 12-week, multicenter, controlled clinical studies

- Epiduo gel, adapalene 0.1% in vehicle gel, benzoyl peroxide 2.5% in vehicle gel, or vehicle gel

• Median age: 15 years old and 60% male (Study 1) and 16 years old and 49% male (Study 2)

Investigator's Global Assessment

		20 to 50 inflammatory lesions and 30 to 100 non-inflammatory lesions
0	Clear	Residual hyperpigmentation and erythema may be present
1	Almost Clear	A few scattered comedones and a few small papules
2	Mild	Easily recognizable; less than half the face is involved. Some comedones and some papules and pustules. No nodules present
3	Moderate	More than half of the face is involved. Many comedones, papules and pustules. One nodule may be present
4	Severe	Entire face is involved, covered with comedones, numerous papules and pustules and few nodules and cysts

A callout box highlights the range "20 to 50 inflammatory lesions and 30 to 100 non-inflammatory lesions" above the IGA scale table, with a grey arrow pointing from the text to the "Moderate" row. At the bottom of the slide, there is a Galderma logo, a progress bar, the text "Screen 9 of 12", and navigation icons (back, forward, search, etc.).

Narration

Now, we will review the clinical studies presented in the Epiduo gel PI. The safety and efficacy of Epiduo gel applied once daily for the treatment of acne vulgaris were assessed in two 12-week, multicenter, controlled clinical studies of similar design, comparing Epiduo gel to the gel vehicle in subjects with acne. The median age of these subjects was 15 years old and 60% male in Study 1 and 49% male in Study 2. Using the 5-point Investigator Global Assessment, or IGA scale, a majority of subjects had a baseline IGA score of 'Moderate' which corresponded to more than half of the face involved, many comedones, papules and pustules (20 to 50 inflammatory lesions and 30 to 100 non-inflammatory lesions).

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Clinical Studies: Results

The screenshot shows a mobile application interface. At the top, there is a navigation bar with a menu icon, the text "LESSON 2", and the title "Clinical Studies: Results". To the right of the title are icons for help, search, and download, followed by "iDASH". Below the title, there is a list of bullet points describing study results:

- Two grade improvement and rated 'Clear' and 'Almost Clear' at week 12
- Mean absolute change from baseline at week 12 in both inflammatory and non-inflammatory lesion counts

In the center, there are two red rectangular buttons labeled "Efficacy Results Study 1" and "Efficacy Results Study 2". At the bottom of the screen, there is a footer bar with the Galderma logo, a progress bar indicating "Screen 10 of 12", the text "For internal use only. Not to be used or distributed outside of Galderma.", and navigation icons for back, forward, and search.

Narration

Treatment response was defined as the percentage of subjects who had a 2-grade improvement and rated 'Clear' and 'Almost Clear' at week 12 based on the Investigator's Global Assessment (IGA). Treatment response also included the mean absolute change from baseline at week 12 in both inflammatory and non-inflammatory lesion counts. With an IGA score of 'Clear', residual hyperpigmentation and erythema may be present. A patient with an IGA score of 'Almost Clear' could have a few scattered comedones and a few small papules.

Tap each button to review the clinical data shown in the Epiduo gel PI.

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Efficacy Results Study 1

≡ LESSON 2 Clinical Studies: Results ? A→Z ↓ iDASH

- Two grade improvement and rated 'Clear' and 'Almost Clear' at week 12
- Mean absolute change from baseline at week 12 in both inflammatory and non-inflammatory lesion counts

Efficacy Results Study 1 **Efficacy Results Study 2**

Clinical Efficacy of Epiduo Gel at Week 12					STUDY 1
	Epiduo Gel (N = 149)	Adapalene 0.1% in Vehicle Gel (N = 148)	Benzoyl Peroxide 2.5% in Vehicle Gel (N = 149)	Vehicle Gel (N = 71)	
IGA: 2-Grade Improvement and Clear or Almost Clear	32 (21.5%)	18 (12.2%)	18 (12.1%)	4 (5.6%)	
Inflammatory Lesions: Mean Absolute (Percent) Change	16.0 (52.4%)	11.4 (39.9%)	10.5 (35.8%)	9.5 (31.8%)	
Non-inflammatory Lesions: Mean Absolute (Percent) Change	23.4 (45.9%)	15.2 (29.6%)	13.7 (32.2%)	13.2 (27.8%)	

The treatment effect was smaller in subjects with a small number of baseline lesions than in subjects with a large number of baseline lesions.

GALDERMA Screen 10 of 12 For internal use only. Not to be used or distributed outside of Galderma. ◀ ▶ ⌂ ▷

Narration

In Study 1, 21.5% of subjects in the Epiduo gel group experienced a 2-grade improvement and clear or almost clear in the IGA scale at week 12, compared to 12.2% for adapalene 0.1%, 12.1% for benzoyl peroxide 2.5%, and 5.6% for vehicle.

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Efficacy Results Study 2

≡ LESSON 2 Clinical Studies: Results ? A→Z ↓ iDASH

- Two grade improvement and rated 'Clear' and 'Almost Clear' at week 12
- Mean absolute change from baseline at week 12 in both inflammatory and non-inflammatory lesion counts

Efficacy Results Study 1 Efficacy Results Study 2

Clinical Efficacy of Epiduo Gel at Week 12

	Epiduo Gel (N = 415)	Adapalene 0.1% in Vehicle Gel (N = 420)	Benzoyl Peroxide 2.5% in Vehicle Gel (N = 415)	Vehicle Gel (N = 418)
IGA: 2-Grade Improvement and Clear or Almost Clear	125 (30.1%)	83 (19.8%)	92 (22.2%)	47 (11.3%)
Inflammatory Lesions: Mean Absolute (Percent) Change	15.4 (53.4%)	12.3 (41.7%)	13.7 (47.6%)	8.7 (30.2%)
Non-inflammatory Lesions: Mean Absolute (Percent) Change	24.6 (48.1%)	21.0 (40.8%)	19.2 (37.2%)	11.3 (23.2%)

The treatment effect was smaller in subjects with a small number of baseline lesions than in subjects with a large number of baseline lesions.

GA DERMA Screen 10 of 12 For internal use only. Not to be used or distributed outside of Galderma. « ▶ ◁ »

Narration

Study 2 had similar results: 30.1% of patients in the Epiduo gel group experienced a 2-grade improvement on the IGA scale compared to 19.8% for adapalene 0.1% group, 22.2% in the benzoyl peroxide 2.5% group, and 11.3% for vehicle.

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Pediatric Clinical Study

≡ LESSON 2 Pediatric Clinical Study ? A→Z ↓ iDASH

- 285 pediatric subjects 9 to 11 years of age
- Randomized to Epiduo gel or vehicle gel; median age = 11 years, 24% males
- Minimum of 20 but not more than 100 total lesions (inflammatory and non-inflammatory)
- IGA score of moderate

STUDY 3		
	Epiduo Gel (N = 142)	Vehicle Gel (N = 143)
IGA: Two Grade Improvement and Clear or Almost Clear	67 (47.2%)	22 (15.4%)
Inflammatory Lesions: Mean Absolute (Percent) Change	7.4 (36.0%)	0.7 (-13.2%)*
Non-inflammatory Lesions: Mean Absolute (Percent) Change	20.2 (54.7%)	2.9 (2.3%)

* - That is, a mean percent increase of 13.2%.

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Narration

A third study evaluated 285 pediatric subjects 9 to 11 years of age. Subjects were randomized to Epiduo gel or vehicle gel. The median age of subjects was 11 years and 24% were males. Subjects had a minimum of 20 but not more than 100 total lesions (inflammatory and non-inflammatory) with an IGA score of moderate at baseline. 47.2% of patients in the Epiduo gel group had a 2-grade improvement and clear or almost clear in the IGA scale compared to 15.4% for the vehicle group. The mean absolute change from baseline in inflammatory lesions was 36.0% for the Epiduo gel group compared to minus 13.2%, that is, a mean percent increase of 13.2%. Take a moment to review the results in the table. When finished, tap the forward button to continue.

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How Supplied

≡ LESSON 2 How Supplied ? A→Z ↓ iDASH



45-gram pump

GALDERMA Screen 12 of 12
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Narration

Epiduo (adapalene and benzoyl peroxide) gel 0.1% / 2.5% is supplied as a 45-gram pump.

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Lesson 3 Learning Objectives

The screenshot shows a mobile application interface. At the top, there is a navigation bar with three horizontal lines followed by "LESSON 3", the text "Lesson Three Learning Objective", and icons for help (?), alphabetical sorting (A→Z), download (down arrow), and iDASH. The main content area features a large, semi-transparent circular graphic with a stylized "H" or "I" shape inside. Overlaid on this graphic is the text "Summarize the data from the phase 3 pivotal trials" in a large, bold, black font. At the bottom of the screen, there is a footer bar with the Galderma logo, a progress bar indicating "Screen 1 of 18", the text "For internal use only. Not to be used or distributed outside of Galderma.", and four navigation icons: a left arrow, a right arrow, a circular arrow, and a double right arrow.

Narration

When you are out in the field, doctors may have questions about the safety and effectiveness of Epiduo gel as an acne treatment. In this lesson, we will review the phase 3 clinical data so that you are prepared for these kinds of questions. By the end of this lesson, you will be able to summarize the data from the phase 3 pivotal trials.

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Phase 3 Study 2

LESSON 8 Phase 3 Study 2 ? A-Z iDASH

Objective Study Design Subject Demographics Assessments

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Narration

The first phase 3 study we will review is referred to in the package insert as study 2. It was published by Gollnick, et al, in the British Journal of Dermatology in 2009. Tap each button to learn more about this study.

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Objectives

The screenshot shows a navigation bar at the top with 'LESSON 3' (highlighted in orange), 'Phase 3 Study 2', a search icon, and filters for 'A-Z', 'iDASH', 'Subject Demographics', and 'Assessments'. Below the bar, the word 'Objective' is highlighted in orange. A main content area displays the study's objective: 'Evaluate the efficacy and safety of adapalene 0.1%-BPO 2.5% fixed-combination topical gel relative to monotherapy of adapalene 0.1%, benzoyl peroxide 2.5%, and vehicle in a large population for the treatment of acne vulgaris for up to 12 weeks'. At the bottom, there is a footer with the Galderma logo, a progress bar, the text 'Screen 2 of 18', and navigation icons.

LESSON 3 Phase 3 Study 2 ? A→Z iDASH

Objective Study Design Subject Demographics Assessments

Objective

- Evaluate the efficacy and safety of adapalene 0.1%-BPO 2.5% fixed-combination topical gel relative to monotherapy of adapalene 0.1%, benzoyl peroxide 2.5%, and vehicle in a large population for the treatment of acne vulgaris for up to 12 weeks

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Narration

The objective of this phase 3 study was to evaluate the efficacy and safety of adapalene 0.1%-benzoyl peroxide (BPO) 2.5% fixed-combination topical gel relative to monotherapy of adapalene 0.1%, benzoyl peroxide 2.5%, and vehicle in a large population for the treatment of acne vulgaris for up to 12 weeks.

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Study Design

LESSON 8 Phase 3 Study 2 ? A-Z ↓ iDASH

Objective Study Design Subject Demographics Assessments

Study Design

- Randomized, multicenter, double-blind, active- and vehicle-controlled parallel group study was conducted at 61 centers in the United States, Canada, and Europe.



```
graph TD; A[Randomized N = 1670] --> B[Adapalene-BPO once daily n = 419]; A --> C[Adapalene once daily n = 418]; A --> D[BPO once daily n = 418]; A --> E[Vehicle once daily n = 418]
```

- Patients applied one of the agents once daily for 12 weeks
- Clinical evaluations were performed at baseline and weeks 1, 2, 4, 8, and 12

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Narration

A randomized, multicenter, double-blind, active- and vehicle-controlled parallel group study was conducted at 61 centers in the United States, Canada, and Europe. Patients were randomized to receive one of the following:

- Adapalene/benzoyl peroxide combination therapy (n = 419)
- Adapalene monotherapy (n = 418)
- Benzoyl peroxide monotherapy (n = 415)
- Gel vehicle (n = 418)

Patients applied one of the agents once daily for 12 weeks. Clinical evaluations were performed at baseline and weeks 1, 2, 4, 8, and 12.

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Subject Demographics

The screenshot shows a navigation bar at the top with 'LESSON 3' selected. Below the navigation bar is a table titled 'Subject Demographics' with five rows corresponding to the IGA scale levels 0 through 4.

0	Clear	Residual hyperpigmentation and erythema may be present
1	Almost Clear	A few scattered comedones and a few small papules
2	Mild	Easily recognizable; less than half the face is involved and some papules and pustules
3	Moderate	More than half of the face is involved; many comedones, papules and pustules; one nodule may be present
4	Severe	Entire face is involved, covered with comedones, numerous papules and pustules, and few nodules and cysts

At the bottom of the screen, there is a footer with the Galderma logo, a progress bar indicating 'Screen 2 of 18', and navigation icons for back, forward, and search.

Narration

Eligible subjects were 12 years or older with moderate acne based on the IGA and with 20 to 50 inflammatory facial lesions and 30 to 100 non-inflammatory facial lesions. Subjects with zero or 1 nodule could also be included. The IGA scale is a 5-grade assessment in which the investigator scores acne on a scale of 0 to 4. In this scale, 0 is clear, 1 is almost clear, 2 is mild, 3 is moderate, and 4 is severe. Take a minute to review the descriptions of the IGA scale before moving on.

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Assessments

LESSON 3 Phase 3 Study 2 ? A→Z ⌂ iDASH

Objective ▾ Study Design ▾ Subject Demographics ▾ Assessments ▾

Assessments

Subject's Assessment of Acne Improvement	
Grade	Description
0	Complete improvement
1	Marked improvement
2	Moderate improvement
3	Minimal improvement
4	No Change
5	Worse

Efficacy Assessments

- Success rate (defined as clear or almost clear) on the IGA scale of acne severity
- Percent change in lesion counts
- Change in IGA
- Subject's assessment of acne improvement

Safety Assessments

- Local cutaneous tolerability assessments
 - Erythema, scaling, dryness, stinging/burning
- Reported adverse events

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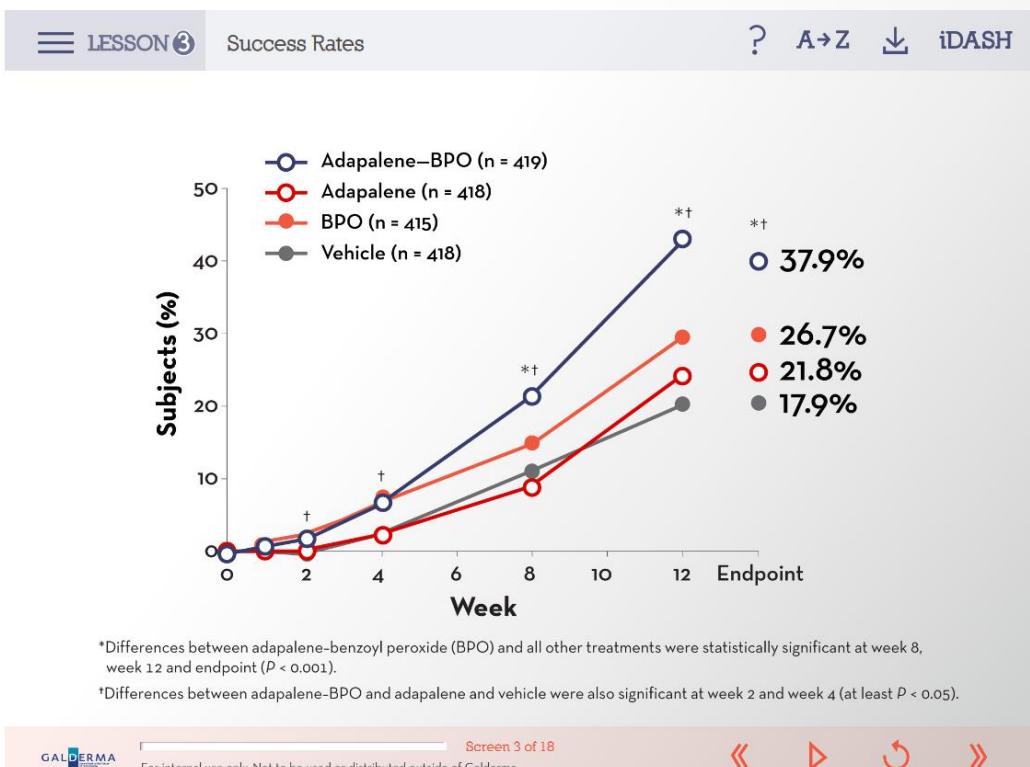
Narration

Efficacy assessments were the success rate (defined as clear or almost clear) on the IGA scale of acne severity, percent change in lesion counts, change in IGA, and subject's assessment of acne improvement. The subject's assessment was evaluated on a scale from 0 (complete improvement) to 5 (worse) as well as through a satisfaction questionnaire. Safety assessments were also done at each visit through evaluations of local cutaneous tolerability, including erythema, scaling, dryness and stinging/burning, as well as adverse events.

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Efficacy Assessment: Success Rates



Narration

First, let's look at the success rates, that is, the percentage of subjects rated "clear" or "almost clear" during the course of the study. The efficacy results showed a significant early treatment effect starting at week 2 that was sustained until the end of the study. At endpoint week 12 – Last Observation Carried Forward, there was a 37.9% success rate with the adapalene-BPO combination compared to 21.8% for adapalene, 26.7% for BPO, and 17.9% for vehicle, $P < 0.001$.

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Median Percentage Change in Lesion Count

≡ LESSON ③ Median Percentage Change in Lesion Count ? A→Z ⌂ iDASH

	Treatment Group			
	Adapalene-BPO (n = 419)	Adapalene (n = 418)	BPO (n = 415)	Vehicle (n = 418)
Median percentage (%) change in lesion count				
Total	-65.4	-52.3	-48.2	-37.1
Inflammatory	-70.3	-57.1	-61.9	-45.5
Non-inflammatory	-62.2	-50.4	-48.8	-36.7
IGA: subjects with "clear", "almost clear", or "mild", (%)	75	63	59	53
Subject assessment (%): subjects with "complete improvement" or "marked improvement", (%)	50	44	39	29

*Adapalene-BPO combination was significantly superior to adapalene, BPO, and vehicle in inflammatory, non-inflammatory, and total lesions; $P < 0.001$.

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Narration

Additional efficacy assessments included the median percent change in lesion count. At week 12, the adapalene-BPO combination was significantly superior to adapalene, BPO, and vehicle in inflammatory, non-inflammatory, and total lesions; $P < 0.001$. Significantly larger reductions in total, inflammatory, and non-inflammatory lesions were observed starting at week 1 compared to the other treatment arms. The exception was adapalene-BPO vs BPO alone, which showed reductions starting at week 2. Take a few minutes to review the table. When finished, tap the forward button to continue.

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Investigator's Global Assessment



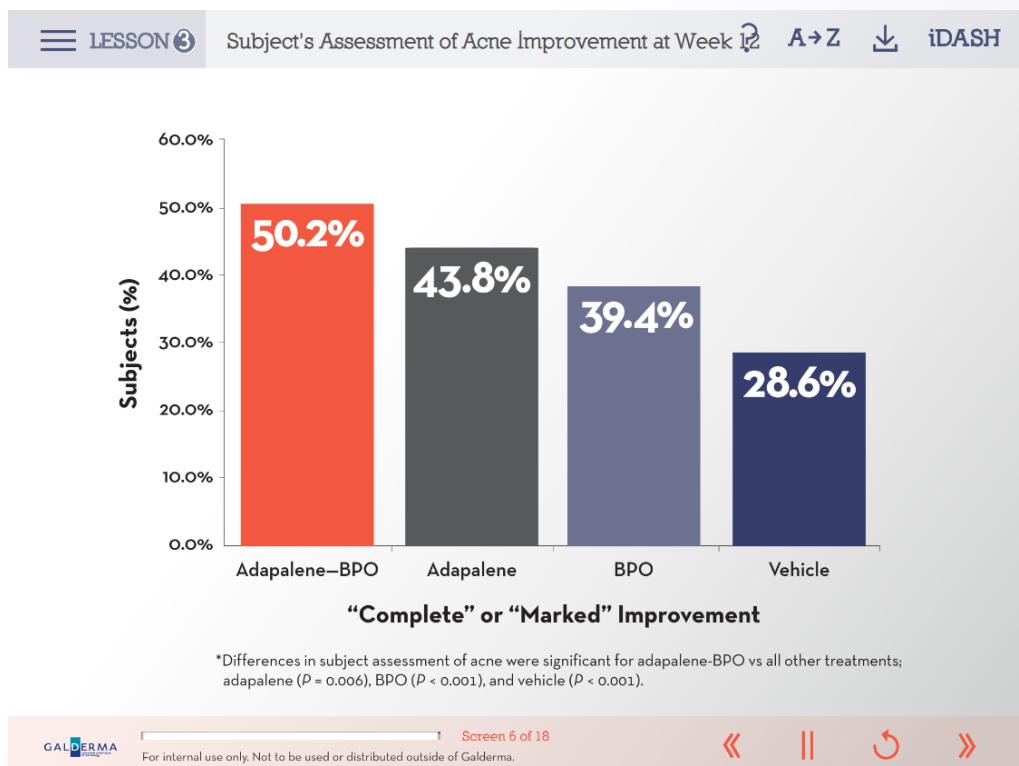
Narration

For IGA, the percentage of subjects with clear, almost clear or mild acne at week 12 are shown here. There was a statistically significant improvement with the adapalene-BPO combination compared to all other treatments; 75.0% in the adapalene-BPO group had an IGA of mild, almost clear, or clear compared with 62.5% for adapalene, 58.8% for BPO, and 52.6% for vehicle. In addition, the number of patients with moderate acne vulgaris decreased from 100% at baseline to 22.9% with adapalene-BPO.

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Subject's Assessment of Acne Improvement



Narration

The other efficacy assessment of interest was the subjects' rating of acne improvement at week 12. Improvement after treatment was rated as "complete" or "marked" improvement by 50.2% in the adapalene-BPO group compared with 43.8% for adapalene, 39.4% for BPO, and 28.6% for vehicle. The results confirmed the investigator's efficacy evaluations.

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Safety Results

The screenshot shows a slide from an eLearning system. At the top, there's a navigation bar with icons for 'LESSON 3' (highlighted in blue), 'Safety Results', and other functions like '?', 'A-Z', 'iDASH'. The main content area contains a bulleted list of safety findings:

- The majority of treatment-related adverse events were skin-related and mild to moderate in severity
- Most of these adverse events occurred early in treatment and resolved without residual effects
- The most frequent treatment-related adverse event was dry skin, followed by contact dermatitis

At the bottom of the slide, there's a footer with the Galderma logo, a progress bar indicating 'Screen 7 of 18', and text stating 'For internal use only. Not to be used or distributed outside of Galderma.' To the right are navigation icons: back, forward, and a circular arrow.

Narration

The majority of treatment-related adverse events were skin-related and mild to moderate in severity. Most of these adverse events occurred early in treatment and resolved without residual effects. The most frequent treatment-related adverse event was dry skin, followed by contact dermatitis.

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Conclusions

The image shows a screenshot of an eLearning platform. At the top, there is a navigation bar with the text 'LESSON 3' and 'Conclusions'. To the right of the navigation bar are icons for help ('?'), alphabetical sorting ('A-Z'), download ('down arrow'), and iDASH. The main content area contains a bulleted list of conclusions. At the bottom of the slide, there is a footer with the Galderma logo, a progress bar indicating 'Screen 8 of 18', and navigation arrows.

- Adapalene-BPO combination is safe, well tolerated, and provides significantly greater efficacy for the treatment of acne vulgaris and a faster onset of action relative to adapalene and BPO monotherapy
- Adapalene/benzoyl peroxide combination was significantly more successful (defined as clear or almost clear) than all other treatments in the treatment of acne lesions at week 12
- Adapalene/benzoyl peroxide combination was associated with significantly greater change in percentage of total, inflammatory, and non-inflammatory lesion counts compared with all other treatment groups
- The majority of treatment-related adverse events were skin related and mild to moderate in severity
- The most common adverse event was dry skin, followed by contact dermatitis

Narration

In summary, the fixed-dose combination of adapalene and BPO is safe, well tolerated, and provides significantly greater efficacy for the treatment of acne vulgaris and a faster onset of action relative to adapalene and BPO monotherapy. Adapalene/benzoyl peroxide combination was significantly more successful (defined as clear or almost clear) than all other treatments in the treatment of acne lesions at week 12. Adapalene/benzoyl peroxide combination was associated with significantly greater change in percentage of total, inflammatory, and non-inflammatory lesion counts compared with all other treatment groups. The majority of treatment-related adverse events were skin-related and mild to moderate in severity. The most common adverse event was dry skin, followed by contact dermatitis.

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Phase 3 Long-term Safety and Efficacy Study

LESSON 3 Phase 3 Long-term Safety and Efficacy Study ? A→Z iDASH

Objective Study Design Subject Demographics Assessments

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Narration

Next, we'll review the long-term safety and efficacy study conducted by Pariser et al. Tap each button to learn more.

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Objective

The screenshot shows a header with 'LESSON 3' and 'Phase 3 Long-term Safety and Efficacy Study'. Below the header are four tabs: 'Objective' (highlighted in red), 'Study Design', 'Subject Demographics', and 'Assessments'. The main content area is titled 'Objective' and contains a bullet point: 'Evaluate the long-term (up to 12 months) safety and efficacy of the adapalene 0.1%-BPO 2.5% fixed-dose combination gel for the treatment of acne vulgaris'. At the bottom, there is a Galderma logo, a progress bar, the text 'Screen 9 of 18', and navigation icons.

LESSON 3 Phase 3 Long-term Safety and Efficacy Study ? A→Z iDASH

Objective Study Design Subject Demographics Assessments

Objective

- Evaluate the long-term (up to 12 months) safety and efficacy of the adapalene 0.1%-BPO 2.5% fixed-dose combination gel for the treatment of acne vulgaris

Screen 9 of 18

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Narration

The objective of this study was to evaluate the long-term (up to 12 months) safety and efficacy of the adapalene 0.1% and benzoyl peroxide (BP) 2.5% fixed-dose combination gel for the treatment of acne vulgaris.

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Study Design

The screenshot shows a navigation bar at the top with 'LESSON 3' (highlighted in blue), 'Phase 3 Long-term Safety and Efficacy Study' (in grey), a help icon, and search/refresh/IDASH buttons. Below is a row of four tabs: 'Objective' (grey), 'Study Design' (red, selected), 'Subject Demographics' (grey), and 'Assessments' (grey). The main content area is titled 'Study Design' and contains a bulleted list of study details. At the bottom is a footer with the Galderma logo, a progress bar, 'Screen 9 of 18', and navigation icons.

Study Design

- A multicenter, open-label, single-arm study was conducted at 28 centers in the US between February 17, 2004 and May 23, 2005
- Subjects with acne vulgaris applied once-daily adapalene/BP to the face for up to 12 months
- Safety and efficacy evaluations were performed at baseline, week 1, week 2, and at months 1, 2, 4, 6, 8, 10, and 12

Narration

A multicenter, open-label, single-arm study was conducted at 28 centers in the US between February 17, 2004 and May 23, 2005. Subjects with acne vulgaris applied once-daily adapalene/BP to the face for up to 12 months, Safety and efficacy evaluations were performed at baseline, week 1, week 2, and at months 1, 2, 4, 6, 8,10, and 12.

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Subject Demographics

The screenshot shows a navigation bar at the top with 'LESSON 3' (highlighted in blue), 'Phase 3 Long-term Safety and Efficacy Study', a search icon, 'A-Z' (sorted by A), a download icon, and 'iDASH'. Below this is a menu bar with four items: 'Objective' (dropdown), 'Study Design' (dropdown), 'Subject Demographics' (selected, highlighted in red), and 'Assessments' (dropdown). The main content area is titled 'Subject Demographics' and contains a table with demographic data for 452 subjects.

Variable	Total (N = 452)	Variable	Total (N = 452)
Gender		Race	
Male	222 (49.1%)	Caucasian	345 (76.3%)
Female	230 (50.9%)	Black	53 (11.7%)
Age (Years)		Asian	
Mean	18.3	Hispanic	31 (6.9%)
SD	6.62	Other	13 (2.9%)
Median	16.0	Skin Phototype	
Min, Max	12, 50	I	12 (2.7%)
Age Category (Years)		II	105 (23.2%)
12 to 17	299 (66.2%)	III	162 (35.8%)
18 and above	153 (33.8%)	IV	87 (19.2%)
Lesion Counts (median)		V	61 (13.5%)
Inflammatory	27.0	VI	25 (5.5%)
Non-inflammatory	42.0	*Median total lesion counts may not equal the sum of median inflammatory and median non-inflammatory.	
Total*	72.0		

Screen 9 of 18
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Narration

Eligible subjects included 452 predominantly Caucasian male and female patients aged 12 to 50 years with 30 to 100 non-inflammatory facial lesions and 20 to 50 inflammatory facial lesions. No patient had active nodules or cysts. No subjects discontinued due to lack of efficacy and discontinuations due to adverse events were low (2.0%). Take a few minutes to review the baseline demographic and clinical characteristics in the table.

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Assessments

The screenshot shows a navigation bar at the top with 'LESSON 3' selected. Below it is a horizontal menu with four items: 'Objective', 'Study Design', 'Subject Demographics', and 'Assessments', where 'Assessments' is highlighted in red. The main content area is titled 'Assessments' and contains two sections: 'Efficacy Assessments' and 'Safety Assessments'. Each section has a bulleted list of items. At the bottom of the screen, there is a footer with the Galderma logo, a progress bar, the text 'Screen 9 of 18', and icons for navigation.

Assessments

Efficacy Assessments

- Percent reduction from baseline in facial lesion counts (total, inflammatory, and non-inflammatory)
- Subject's assessment of acne improvement on a scale of 0 (complete improvement) to 5 (worse)

Safety Assessments

- Local facial tolerability (erythema, scaling, dryness, and stinging/burning) on a scale from 0 (none) to 3 (severe)
- Reported adverse events

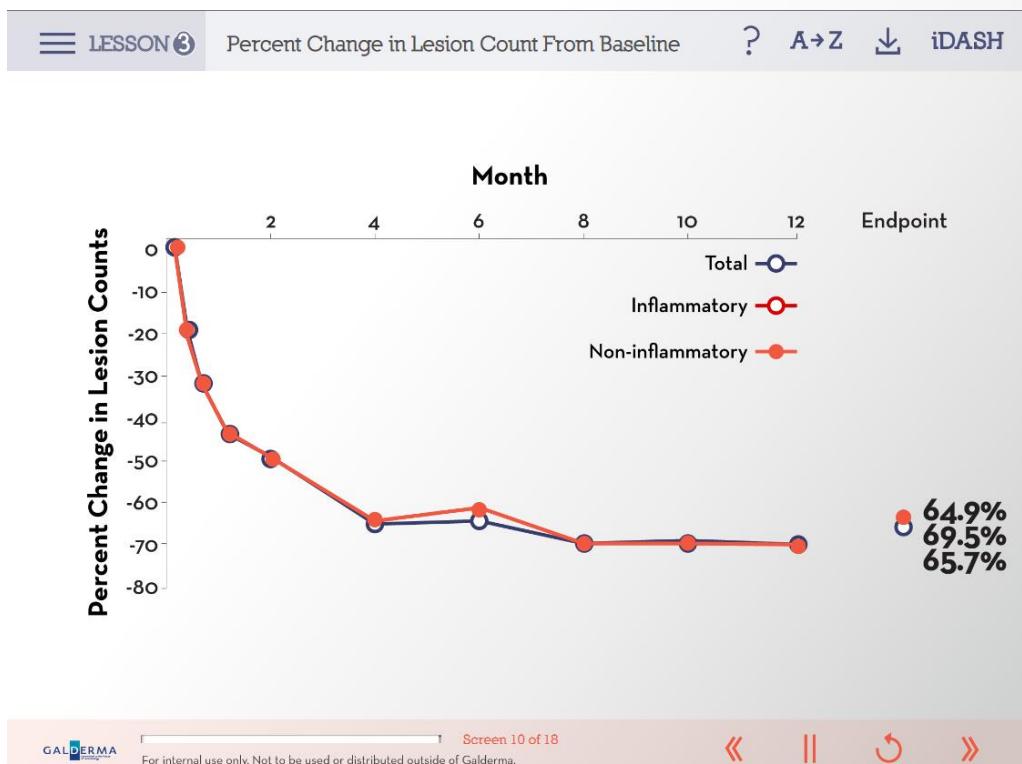
Narration

The efficacy assessments were percent lesion count reduction from baseline (total, inflammatory, and non-inflammatory) and subject's assessment of acne (on a scale from 0 [complete improvement] to 5 [worse]). Lesion counts were assessed on the face only, excluding the nose. Safety and tolerability were assessed through evaluations of cutaneous tolerability and adverse events at each visit. The investigator rated erythema, scaling, dryness, and stinging/burning on a scale ranging from 0 (none) to 3 (severe). Adverse events were also assessed at each visit.

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Percent Change in Lesion Count From Baseline



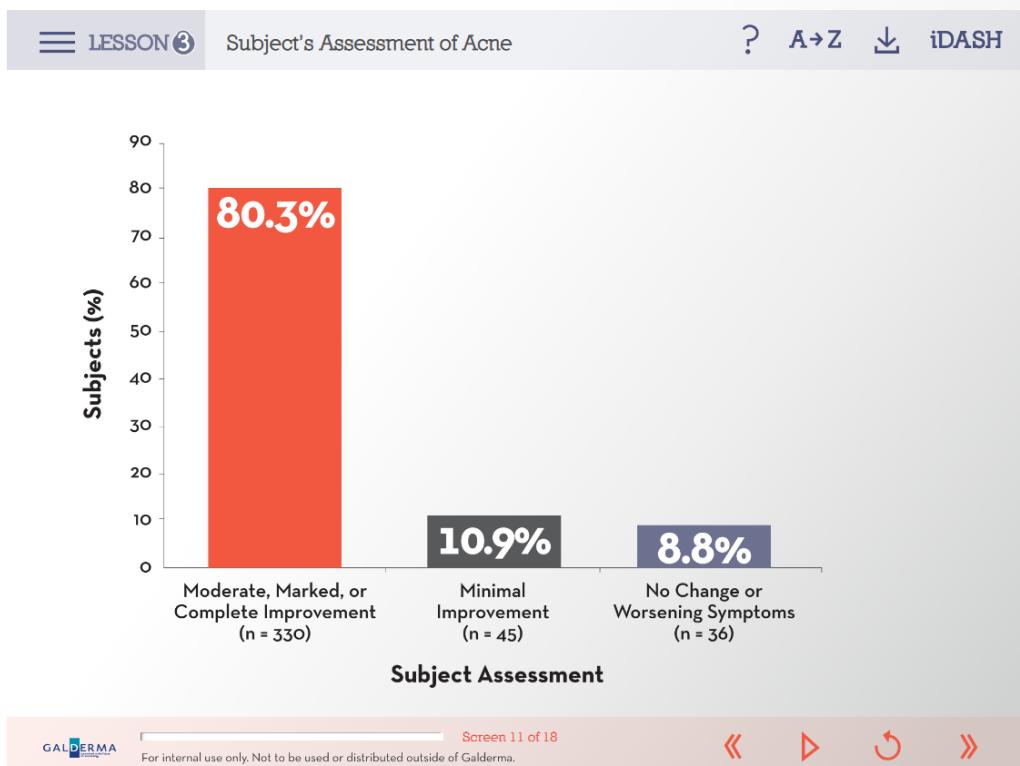
Narration

Now let's discuss some of the key results in this long-term study. The first efficacy variable observed was the percent lesion count reduction from baseline. The results showed that for the 327 subjects who remained in the study until the 12-month visit, the median percent reductions from baseline were 70.8% for total, 76% for inflammatory, and 70% for non-inflammatory lesion counts. Taking into consideration the last observation carried forward, the median percent reductions from baseline for total, inflammatory, and non-inflammatory lesion counts were 64.9%, 69.5%, and 65.7%, respectively. Reductions were observed starting as early as week 1. Lesion counts continued to decrease through the initial 4 months and were maintained for the duration of the study.

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Subject's Assessment of Acne



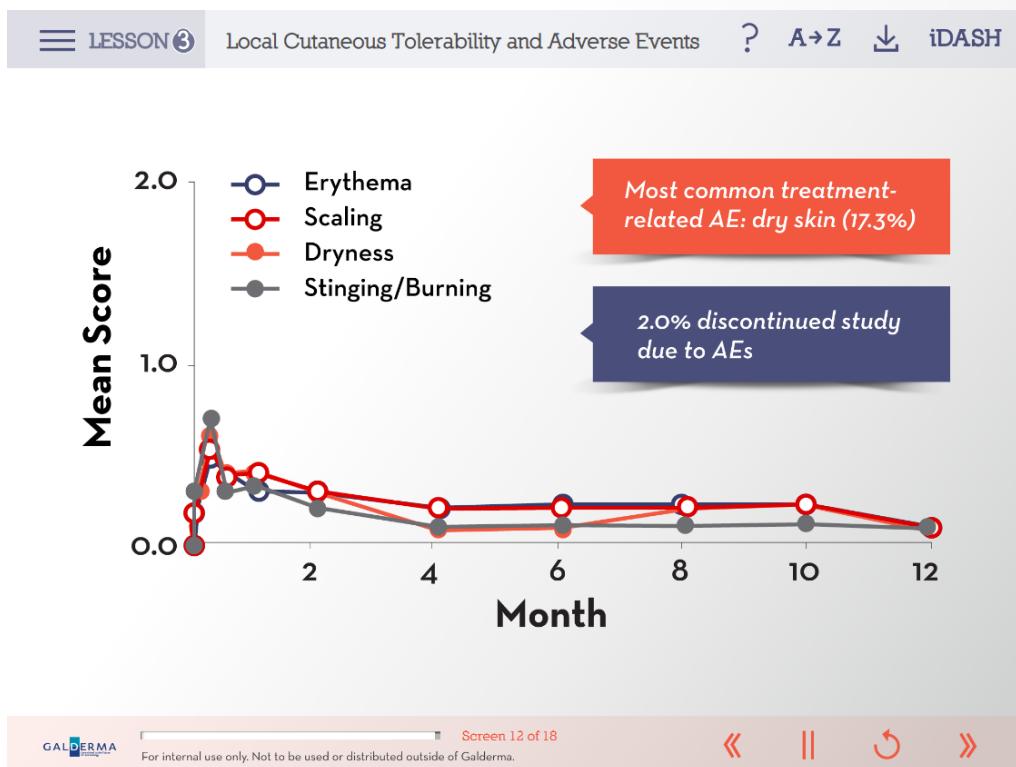
Narration

The second efficacy variable was the subject's assessment of acne. Subject's rated their acne on a scale from 0 [complete improvement] to 5 [worse]. At the end of the study, adapalene-BPO treatment demonstrated a clinical improvement over the 12 months of treatment. 80.3% of subjects reported moderate, marked, or complete improvement, while only 10.9% reported a minimal improvement, and 8.8% reported no change or worsening.

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Local Cutaneous Tolerability and Adverse Events



Narration

Safety assessments included local cutaneous tolerability and adverse events.

Overall, treatment with adapalene/BPO was safe and well tolerated when used for up to 12 months in subjects with acne vulgaris. Skin tolerability variables included erythema, scaling, dryness, and stinging/burning, and were assessed according to the following scoring scale: 0 (none), 1 (mild), 2 (moderate), and 3 (severe). The mean tolerability scores were all mild (<1) at each study visit. The highest scores were recorded at the week 1 visit and then decreased to levels similar to baseline scores. .

The majority of adverse events were mild or moderate in severity. The most common treatment-related adverse event was dry skin (17.3%). Most AEs occurred within the first 3 months of therapy and the incidence dropped at subsequent visits. During the 12-month study, dermatological AEs that led to discontinuation occurred in only 2.0% of subjects, and no subjects discontinued due to lack of efficacy.

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Conclusions

The image shows a screenshot of an eLearning platform. At the top, there is a navigation bar with icons for 'LESSON 3' (highlighted in blue), 'Conclusions', a question mark, 'A-Z', a download arrow, and 'iDASH'. Below the navigation bar, the main content area displays a bulleted list of conclusions from a study. The list includes: 'Overall, the results of the study support the safe and effective use of the fixed-dose combination gel of adapalene and BPO for the long-term management of acne vulgaris'; 'Clinically significant inflammatory and non-inflammatory lesion count reductions were observed as early as week 1 and continued to improve up to 1 year'; 'Eighty percent of subjects reported moderate, marked, or complete improvement of their acne'; and 'Most adverse events and symptoms of skin irritation were mild to moderate, occurred early in the study, and decreased thereafter'. At the bottom of the content area, there is a footer bar with the Galderma logo, a progress bar, the text 'Screen 13 of 18', the instruction 'For internal use only. Not to be used or distributed outside of Galderma.', and navigation icons (back, forward, search, etc.).

- Overall, the results of the study support the safe and effective use of the fixed-dose combination gel of adapalene and BPO for the long-term management of acne vulgaris
- Clinically significant inflammatory and non-inflammatory lesion count reductions were observed as early as week 1 and continued to improve up to 1 year
- Eighty percent of subjects reported moderate, marked, or complete improvement of their acne
- Most adverse events and symptoms of skin irritation were mild to moderate, occurred early in the study, and decreased thereafter

Narration

The investigators concluded that, overall, the results of the study support the safe and effective use of the fixed-dose combination gel of adapalene and BPO for the long-term management of acne vulgaris. Clinically significant inflammatory and non-inflammatory lesion count reductions were observed as early as week 1 and continued to improve for up to 1 year. Eighty percent of subjects reported moderate, marked, or complete improvement of their acne. Most adverse events and symptoms of skin irritation were mild to moderate, occurred early in the study, and decreased thereafter.

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Phase III Study in Pediatric Patients

The screenshot shows the eLearning system interface. At the top, there is a navigation bar with the title "Phase III Study in Pediatric Patients". Below the title, there are four main menu items: "Objective" (selected), "Study Design", "Subject Demographics", and "Assessments". To the right of these menu items are icons for help (?), A to Z (alphabetical sort), download (down arrow), and iDASH. At the bottom of the screen, there is a footer bar with the Galderma logo, a progress bar indicating "Screen 14 of 18", and navigation arrows for previous, next, first, and last screens.

Narration

Now, we'll review the phase 3 study of adapalene 0.1%-benzoyl peroxide 2.5% gel in pediatric patients.
Tap each button to learn more.

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Objective

The screenshot shows a header with 'LESSON 3' and 'Phase III Study in Pediatric Patients'. Below is a navigation bar with four tabs: 'Objective' (highlighted in red), 'Study Design', 'Subject Demographics', and 'Assessments'. The main content area displays the title 'Objective' and the study's purpose: 'Evaluate the efficacy and safety of adapalene 0.1%-benzoyl peroxide 2.5% gel in patients 9 to 11 years old with acne vulgaris'. At the bottom, there is a Galderma logo, a progress bar, and navigation icons.

LESSON 3 Phase III Study in Pediatric Patients

?

A→Z

iDASH

Objective

Study Design

Subject Demographics

Assessments

Objective

Evaluate the efficacy and safety of adapalene 0.1%-benzoyl peroxide 2.5% gel in patients 9 to 11 years old with acne vulgaris

GALDERMA Screen 14 of 18

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Narration

The objective of this phase 3 study was to evaluate the efficacy and safety of adapalene 0.1%-benzoyl peroxide 2.5% gel in patients 9 to 11 years old with acne vulgaris.

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Study Design

The screenshot shows a navigation bar at the top with 'LESSON 3' and 'Phase III Study in Pediatric Patients'. Below the bar are four tabs: 'Objective' (grey), 'Study Design' (red, selected), 'Subject Demographics' (grey), and 'Assessments' (grey). The main content area is titled 'Study Design' and contains a bulleted list of study details. At the bottom, there is a footer with the Galderma logo, a progress bar, 'Screen 14 of 18', and navigation icons.

Study Design

- Multicenter, randomized, vehicle-controlled, double-blind study
- Conducted at 20 centers in the US and 5 centers in Canada
- Randomized to receive adapalene-BPO fixed-dose combination gel or vehicle gel once daily for up to 12 weeks
- Study visits took place at weeks 1, 2, 4, 8, and 12

GALDERMA Screen 14 of 18
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Narration

A multicenter, randomized, vehicle-controlled, double-blind study was conducted at 20 centers in the US and 5 centers in Canada. Subjects were randomized to receive adapalene-BPO fixed-dose combination gel or vehicle gel once daily in the evening to the face and trunk (if applicable) for up to 12 weeks. Study visits were performed at weeks 1, 2, 4, 8, and 12.

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Subject Demographics

The screenshot shows a digital interface for an eLearning system. At the top, there's a navigation bar with 'LESSON 3' (highlighted in blue), 'Phase III Study in Pediatric Patients', and various search and filter icons. Below this is a menu bar with 'Objective', 'Study Design', 'Subject Demographics' (which is red and highlighted), and 'Assessments'. The main content area is titled 'Subject Demographics' and contains a table comparing Adapalene-BPO (N = 142) and Vehicle (N = 143) across several demographic categories. The table includes columns for 'Gender', 'Age, Year', 'Race, n (%)', 'Investigator's Global Assessment (IGA), n (%)', and 'Mean Lesion Counts'. At the bottom of the table, there's a note about internal use and a footer with Galderma branding and navigation icons.

	Adapalene-BPO (N = 142)	Vehicle (N = 143)	Total (N = 285)
Gender			
Male	222 (49.1%)	222 (49.1%)	222 (49.1%)
Female	222 (49.1%)	222 (49.1%)	222 (49.1%)
Age, Year			
Mean ± SD	10.3 ± 0.76	10.4 ± 0.68	10.4 ± 0.72
9 years old, %	17.6	10.5	14.0
10 years old, %	31.7	34.3	33.0
11 years old, %	50.7	55.2	53.0
Race, n (%)			
Caucasian	81 (57.0)	87 (60.8)	168 (58.9)
Black	36 (25.4)	32 (22.4)	68 (23.9)
Asian	2 (1.4)	1 (0.7)	3 (1.1)
Hispanic	6 (4.2)	5 (3.5)	11 (3.9)
Other	17 (12.0)	18 (12.6)	35 (12.3)
Investigator's Global Assessment (IGA), n (%)			
3 = Moderate	142 (100)	143 (100)	285 (100)
Mean Lesion Counts			
Total	50.5	56.4	53.5
Inflammatory	13.8	16.6	15.2
Non-inflammatory	36.7	39.9	38.3
Truncal lesions, n (%)	28 (19.7)	34 (23.8)	62 (21.8)

Narration

Eligible subjects were 9 to 11 years of age with an IGA score of 3 (moderate) and 20 to 100 total lesions (non-inflammatory and/or inflammatory) on the face, including the nose. The mean inflammatory lesion count was 15.2 and non-inflammatory count was 38.3 (12 and 34 for median counts, respectively). This was consistent with the typical presentation of acne in younger individuals characterized by a predominance of non-inflammatory lesions.

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Assessments

The screenshot shows a digital interface for a study titled "Phase III Study in Pediatric Patients". The top navigation bar includes "LESSON 3", "Phase III Study in Pediatric Patients", a help icon, and search functions. Below the navigation is a menu bar with four items: "Objective" (grey), "Study Design" (grey), "Subject Demographics" (grey), and "Assessments" (orange, indicating the current section). The main content area is titled "Assessments" and contains two sections: "Modified Pediatric IGA Scale" and "Efficacy Assessments".

Modified Pediatric IGA Scale

	Description
0 Clear	<ul style="list-style-type: none">No comedones, papules or pustulesResidual hyperpigmentation and erythema may be present
1 Almost Clear	<ul style="list-style-type: none">Rare comedonesNo more than a few small papules and pustules
2 Mild	<ul style="list-style-type: none">Easily recognizable comedones in limited numbers± Presence of some small papules or pustules
3 Moderate	<ul style="list-style-type: none">Many comedones± Easily recognizable small and medium-sized papulesNo nodules or cysts
4 Severe	<ul style="list-style-type: none">Widespread and numerous comedonesMany small, medium-sized and large papules and pustulesNodules or cysts may or may not be present

Efficacy Assessments

- Primary outcome measures were:
 - IGA success rate, defined as the percentage of subjects rated "clear" or "almost clear" with at least 2 grades' reduction from baseline
 - Change from baseline in total lesion counts at week 12

Safety Assessments

- Reported adverse events
- Local tolerability
 - Erythema, scaling, dryness, stinging/burning rated from 0 (none) to 3 (severe)

At the bottom of the screen, there is a footer with the Galderma logo, a progress bar, the text "Screen 14 of 18", and a note: "For internal use only. Not to be used or distributed outside of Galderma." There are also navigation icons for back, forward, and search.

Narration

Primary efficacy assessments were success rate, defined as the percentage of subjects rated "clear" or "almost clear" with at least 2 grades' reduction from baseline on the IGA at each visit; and the change from baseline in total lesion counts at week 12. It is important to note that a modified IGA scale for pediatrics was used in this study. The modified scale ranged from 0 (clear – no comedones, papules, or pustules) to 4 (severe – widespread and numerous comedones with many small, medium-sized, and large papules and pustules).

Secondary efficacy assessments were the median percentage changes from baseline in total, inflammatory, and non-inflammatory lesion counts at each visit. Also, a quality of life questionnaire and the parent assessment of acne were completed at baseline and at week 12.

Safety assessments included evaluations of adverse events (AEs) and local tolerability, including erythema, scaling, dryness, and stinging/burning on scales ranging from 0 (none) to 3 (severe).

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IGA Success Rate



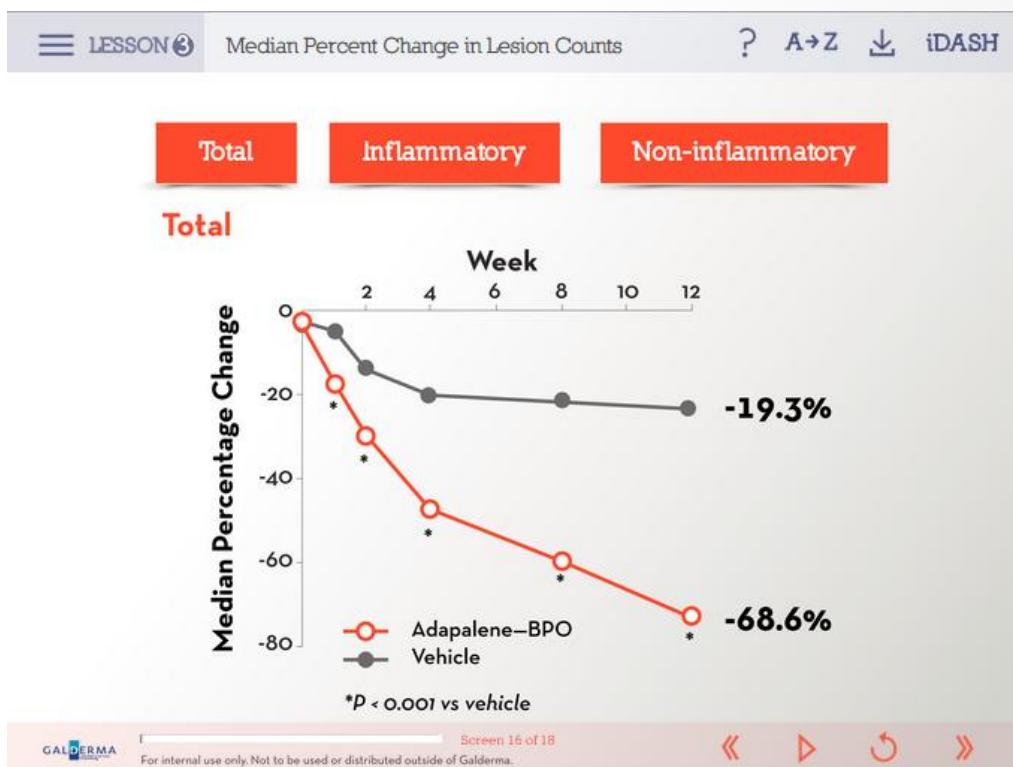
Narration

The first primary outcome measure was success rate, defined as the percentage of subjects rated "clear" or "almost clear" with at least 2 grades' reduction from baseline on the IGA scale at each visit. The efficacy results showed that of the 142 patients randomized to adapalene-BPO and 143 to vehicle, nearly half of the subjects in the adapalene-BPO group were rated "clear" or "almost clear" at study endpoint (week 12) compared to vehicle, 49.3% vs 15.9%, respectively, $P < 0.001$. The success rate for adapalene-BPO increased continuously throughout the study, reaching significance as early as week 4.

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Median Percent Change in Lesion Counts



Narration

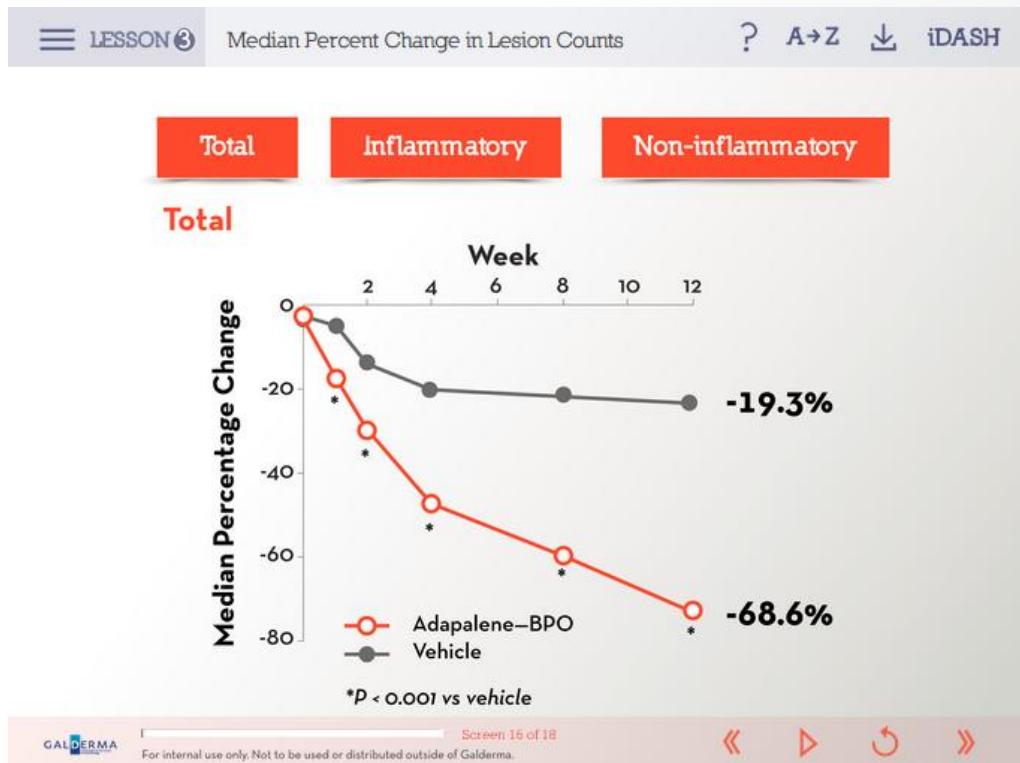
With respect to change from baseline in total lesion counts, adapalene-BPO was significantly more effective than vehicle, 68.6% vs 19.3%, $P < 0.001$. At week 12, adapalene-BPO was also significantly more effective than vehicle for both inflammatory lesion counts (63.2% vs 14.3%) and non-inflammatory lesion counts (70.7% vs 14.6%), $P < 0.001$ for both. Regardless of the lesion type, adapalene-BPO showed a significant decrease in lesion counts as early as week 1 ($P < 0.05$). For the vehicle, however, percentage change plateaued in total and non-inflammatory lesions, and worsened (increased) for inflammatory lesions between weeks 8 and 12.

Tap each button to review the efficacy results for each lesion count type.

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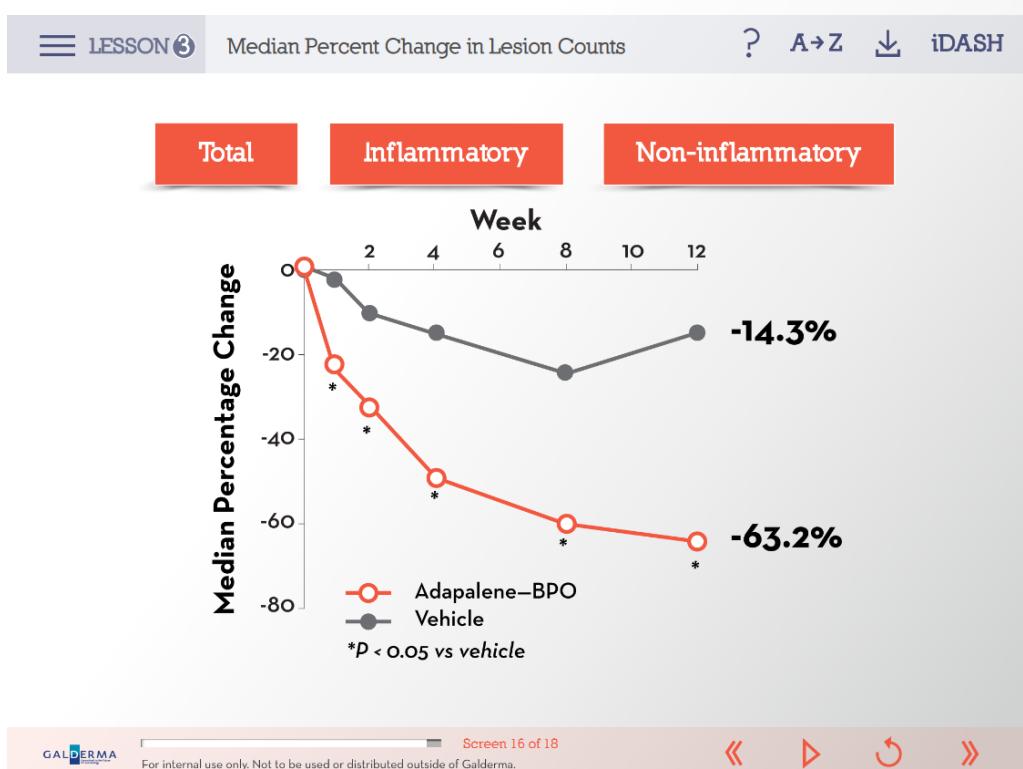
Total



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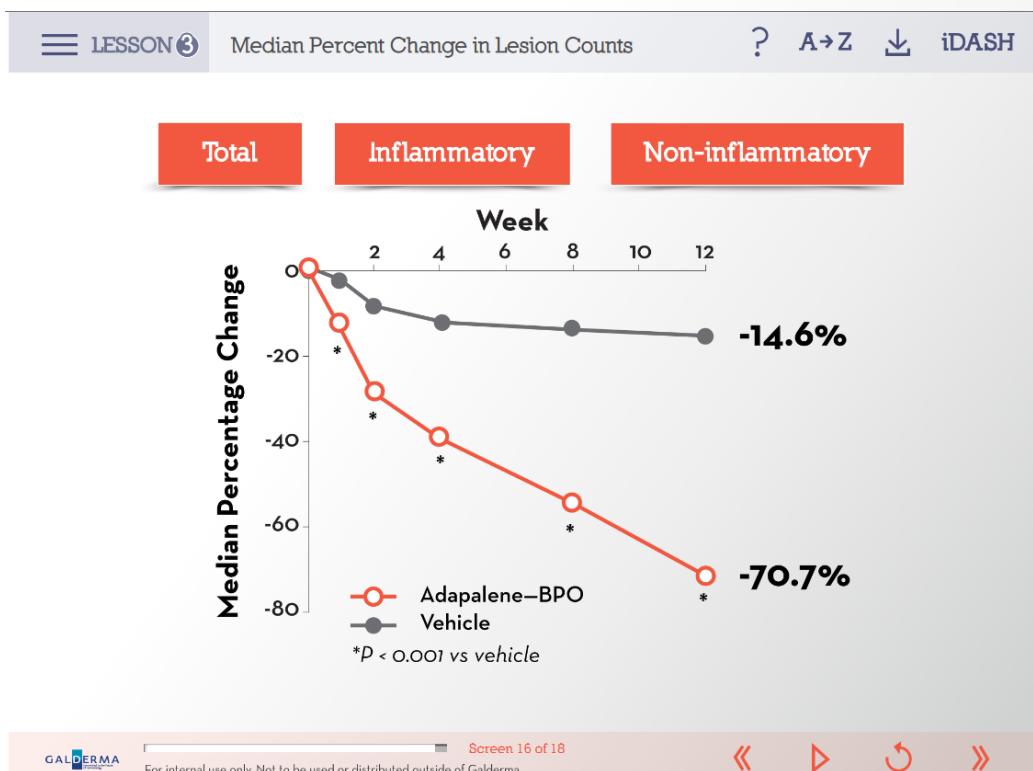
Inflammatory



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Non-inflammatory



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Safety Results

	Adapalene-BPO (n = 142)	Vehicle Cream (n = 143)
Total number of subjects with related AEs, n (%)^a	29 (20.4)	1 (0.7)

Related Adverse Events Included: Skin Burning Sensation (9.2%) and Skin Irritation (5.6%)

- Mean scores and mean worst scores for erythema, scaling, dryness, and stinging/burning did not exceed 1 (mild)
- Mean tolerability scores remained mild and were comparable to vehicle at week 4

Screen 17 of 18
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Narration

Adapalene-BPO was generally well tolerated. A total of 29 subjects (20.4%) experienced treatment-related AEs in the adapalene-BPO group compared with 1 subject (0.7%) in the vehicle group. All treatment-related AEs were skin related; most were transient and mild or moderate in severity. The most common treatment-related AEs were skin burning sensation (9.2%) and skin irritation (5.6%). In both treatment groups, mean scores and mean worst scores for erythema, scaling, dryness, and stinging/burning did not exceed 1 (mild). Mean tolerability scores peaked for adapalene-BPO during the first two weeks of treatment, but remained mild and were comparable to vehicle at week 4.

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Conclusions

The screenshot shows a user interface for an eLearning system. At the top, there is a navigation bar with icons for 'LESSON 3' (with a blue circle containing a white number '3'), 'Conclusions', '?', 'A-Z', a downward arrow, and 'iDASH'. Below the navigation bar is a main content area containing a bulleted list of conclusions. At the bottom of the screen, there is a footer bar with the Galderma logo, a progress bar indicating 'Screen 18 of 18', and navigation icons for back, forward, and search.

- Adapalene-BPO achieved a significantly higher treatment success compared to vehicle as early as week 4
- Adapalene-BPO was also significantly more effective in reducing both inflammatory and non-inflammatory lesions at week 12
- For total, inflammatory and non-inflammatory lesions, results were significantly superior for adapalene-BPO as early as week 1, and remained significant at all time points
- Adapalene-BPO was generally well tolerated, and mean scores and mean worst scores for erythema, scaling, dryness, and stinging/burning did not exceed 1 (mild)

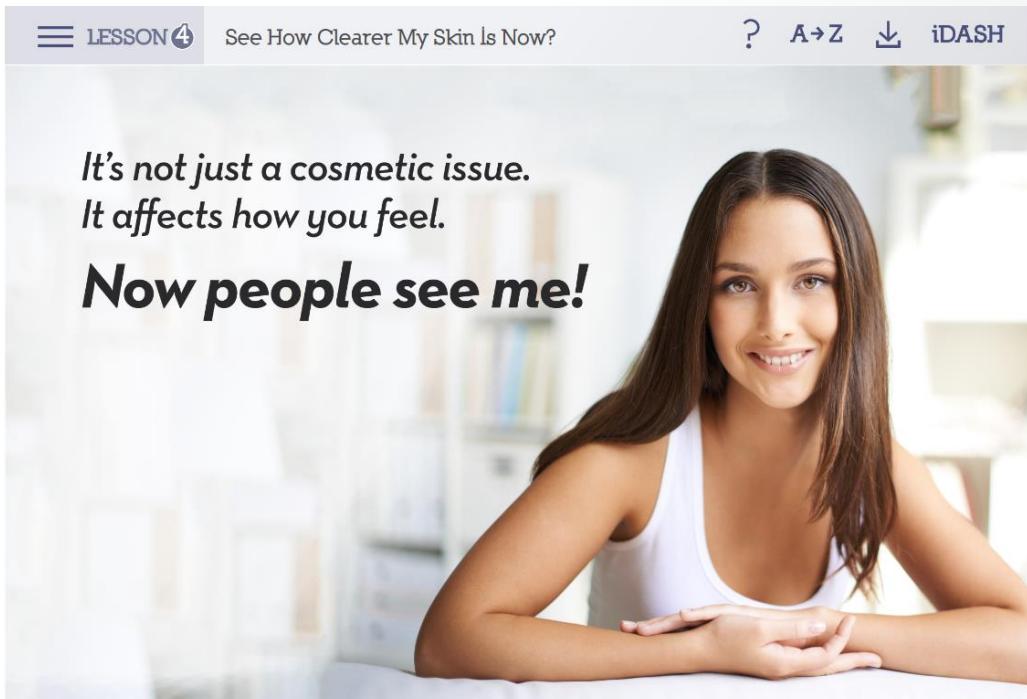
Narration

In summary, results of this randomized controlled trial support the early treatment of acne as reasonable and well tolerated in children between the ages of 9 and 11. Adapalene-BPO achieved a significantly higher treatment success compared to vehicle as early as week 4. Adapalene-BPO was also significantly more effective in reducing both inflammatory and non-inflammatory lesions at week 12. For total, inflammatory and non-inflammatory lesions, results were significantly superior for adapalene-BPO as early as week 1, and remained significant at all time points. Adapalene-BPO was generally well tolerated, and mean scores and mean worst scores for erythema, scaling, dryness, and stinging/burning did not exceed 1 (mild).

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See How Clearer My Skin Is Now?



≡ LESSON 4 See How Clearer My Skin Is Now? ? A→Z ⌂ iDASH

*It's not just a cosmetic issue.
It affects how you feel.*

Now people see me!

GALDERMA Screen 1 of 10
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Narration

I'm not sure a lot of people, especially adults, remember how important it is to have clear skin when you are a teenager. It's not just a cosmetic issue or what my Dad calls "just a hormone problem." Having acne can affect not only how you look, but also how you feel and how other people react to you. Now that I have been on this new medicine, I can tell that people look at me differently. They see me, not my acne. It's about time I felt good about all this. See how clearer my skin is now?

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Lesson Four Learning Objectives

The screenshot shows a grey header bar with a menu icon, the text "LESSON 4", "Lesson Four Learning Objectives", and icons for help, search, download, and iDASH. Below the header is the "EPIDUO® FORTE" logo, which includes the text "(adapalene and benzoyl peroxide) Gel 0.3% / 2.5%" and a stylized orange and blue swoosh. The main content area contains two bullet points: "Discuss the information in the Epiduo Forte gel Package Insert" and "Describe the differences between Epiduo gel and Epiduo Forte gel". At the bottom left is the Galderma logo and the text "For internal use only. Not to be used or distributed outside of Galderma". At the bottom right are navigation icons: a double arrow, a single arrow, a circular arrow, and a double arrow.

- Discuss the information in the Epiduo Forte gel Package Insert
- Describe the differences between Epiduo gel and Epiduo Forte gel

Narration

By the end of this lesson, you will be able to discuss the information in the Epiduo Forte gel Package Insert in a knowledgeable and confident manner, and describe the differences between Epiduo gel and Epiduo Forte gel.

We will only be covering the sections of the PI that are different from the Epiduo gel package insert. Let's start with indications and dosage, and administration. Tap the forward button to continue.

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Epiduo® Gel and Epiduo Forte® Gel eLearning System

Indications and Usage | Dosage and Administration

≡ LESSON 4 Indications and Usage | Dosage and Administration ? A-Z ↓ iDASH

1 INDICATIONS AND USAGE

EPIDUO FORTE gel is indicated for the topical treatment of acne vulgaris.

2 DOSAGE AND ADMINISTRATION

For topical use only. EPIDUO FORTE gel is not for oral, ophthalmic, or intravaginal use.

Apply a thin layer of EPIDUO FORTE gel to affected areas of the face and/or trunk once daily after washing. Use a pea-sized amount for each area of the face (e.g., forehead, chin, each cheek). Avoid the eyes, lips and mucous membranes.

GALDERMA Screen 3 of 10
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Narration

As you have learned, Epiduo gel (adapalene 0.1% and benzoyl peroxide 2.5%) is indicated for the topical treatment of acne vulgaris in patients 9 years of age and older. Epiduo Forte gel uses 0.3% adapalene and 2.5% benzoyl peroxide gel. It is indicated for the topical treatment of acne vulgaris.

As with Epiduo gel, Epiduo Forte is not for oral, ophthalmic, or intravaginal use. A thin layer of Epiduo Forte gel should be applied to affected areas of the face and/or trunk once daily after washing. A pea-sized amount should be used for each area of the face, such as the forehead, chin, and each cheek; and avoid the eyes, lips, and mucous membranes.

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Epiduo® Gel and Epiduo Forte® Gel eLearning System

Dosage Forms and Strength

≡ LESSON 4 Dosage Forms and Strengths ? A-Z ↓ iDASH

3 DOSAGE FORMS AND STRENGTHS

Each gram of EPIDUO FORTE gel contains 3 mg (0.3%) adapalene and 25 mg (2.5%) benzoyl peroxide in a white to very pale yellow, opaque gel. EPIDUO FORTE is available in pumps containing 15 g, 30 g, 45 g, or 70 g.

GALDERMA Screen 4 of 10
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Narration

Epiduo Forte gel contains 2.5% of benzoyl peroxide and **0.3%** of adapalene. Both Epiduo gel and Epiduo Forte gel come in a white to very pale yellow, opaque gel.

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Adverse Reactions

≡ LESSON 4 Adverse Reactions ? A→Z ↓ iDASH

Adverse Reactions Occurring in > 1% of Subjects with Acne Vulgaris in a 12-week Clinical Trial			
System Organ Class/ Preferred Term	Epiduo Forte gel (N = 217)	Adapalene and Benzoyl Peroxide Gel, 0.1%/2.5% (N = 217)	Vehicle gel (N = 69)
Skin irritation	4%	<1%	0%
Eczema	1%	0%	0%
Dermatitis atopic	1%	0%	0%
Skin burning sensation	1%	0%	0%

GALDERMA Screen 5 of 10
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Narration

During the phase 3 clinical trial, 217 subjects were exposed to Epiduo Forte gel. A total of 197 subjects with acne vulgaris, 12 years and older, were treated once daily for 12 weeks. Related adverse events reported within 12 weeks of treatment in at least 1% of subjects treated with Epiduo Forte gel are presented here.

Adverse reactions included skin irritation, eczema, atopic dermatitis, and skin burning sensation.

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Epiduo® Gel and Epiduo Forte® Gel eLearning System

Adverse Reactions

≡ LESSON 4 Adverse Reactions ? A→Z ⌂ iDASH

Incidence of Local Cutaneous Irritation in 12-Week Clinical Trial in Subjects With Acne Vulgaris				
	Maximum Severity During Treatment		End of Treatment (Final Score)	
EPIDUO FORTE Gel (N = 213)				
	Moderate	Severe	Moderate	Severe
Erythema	20%	1%	4%	<1%
Scaling	17%	1%	1%	<1%
Dryness	15%	2%	3%	<1%
Stinging/burning	19%	6%	1%	1%
Adapalene and Benzoyl Peroxide Gel, 0.1%/2.5% (N = 212)				
Erythema	15%	1%	2%	<1%
Scaling	12%	<1%	2%	0%
Dryness	13%	1%	2%	0%
Stinging/burning	14%	9%	3%	0%
Vehicle Gel (N = 68)				
Erythema	6%	1%	1%	0%
Scaling	6%	0%	1%	0%
Dryness	4%	1%	1%	0%
Stinging/burning	3%	1%	0%	0%

GALDERMA Screen 6 of 10
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Narration

Local tolerability evaluations presented in Table 2 were conducted at each study visit in the clinical trial by assessment of erythema, scaling, dryness, and stinging/burning, which peaked at Week 1 of therapy and decreased thereafter.

It is important for healthcare providers to let patients know that most adverse reactions will tend to be mild to moderate and generally resolve as they continue treatment.

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Use in Specific Populations

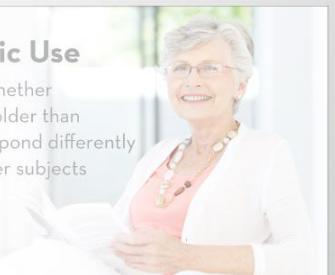
≡ LESSON 4 Use in Specific Populations ? A→Z ⌂ iDASH

Pregnancy 

- Pregnancy category C
- Should be used during pregnancy only if potential benefit justifies risk to fetus

Nursing Mothers 
Caution should be exercised when administered to a nursing woman

Pediatric Use 
Safety and efficacy in pediatric patients under the age of **12** have not been established

Geriatric Use 
Unknown whether individuals older than 65 years respond differently from younger subjects

GALDERMA Screen 7 of 10
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« ▶ ⌂ »

Narration

The section on use in specific populations is similar to the Epiduo gel package insert, including pregnancy, nursing mothers and geriatric use. The one section that is different is Pediatric Use. The safety and effectiveness of Epiduo Forte gel in pediatric patients under the age of 12 has not been established.

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Clinical Studies

LESSON 4 Clinical Studies

?

A→Z

Download

iDASH

Definition of Treatment Response

Patient Characteristics

Study Results

GALDERMA

Screen 8 of 10

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Narration

Now let's look at the Clinical Studies section. The safety and efficacy of Epiduo Forte gel 0.3% applied once daily for 12 weeks for the treatment of acne vulgaris were assessed in a multicenter, randomized, double-blind, controlled study that compared Epiduo Forte gel to gel vehicle in acne subjects. The study also evaluated adapalene and benzoyl peroxide gel, 0.1%/2.5%, a lower strength product than Epiduo Forte gel. Two-hundred and seventeen subjects were treated with Epiduo Forte gel, 217 with adapalene and benzoyl peroxide gel, 0.1%/2.5%, and 69 subjects with the vehicle. It is important to note that 50% of patients had moderate acne and 50% were classified as severe.

Tap each button to learn more about treatment response, the patient characteristics at baseline and the results.

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Epiduo® Gel and Epiduo Forte® Gel eLearning System

Definition of Treatment Response

The screenshot shows a mobile application interface for the Epiduo eLearning System. At the top, there is a navigation bar with icons for a menu (three horizontal lines), 'LESSON 4' (with a blue dot), 'Clinical Studies', a question mark, 'A-Z' (alphabetical order), a downward arrow, and 'iDASH'. Below the navigation bar, there are three main categories: 'Definition of Treatment Response' (highlighted in red), 'Patient Characteristics', and 'Study Results'. Each category has a dropdown arrow icon. The 'Definition of Treatment Response' section is expanded, showing its content. At the bottom of the screen, there is a footer bar with the Galderma logo, a progress bar indicating 'Screen 8 of 10', the text 'For internal use only. Not to be used or distributed outside of Galderma.', and four navigation icons: a double-left arrow, a right arrow, a circular arrow, and a double-right arrow.

Definition of Treatment Response

Treatment response defined as:

- Percent of subjects rated “Clear” and “Almost Clear” at week 12 with at least a 2-grade improvement based on the Investigator’s Global Assessment (IGA)
- Mean absolute change from baseline at week 12 in both inflammatory and non-inflammatory lesion count
- IGA score of “Clear” corresponded to clear skin with no inflammatory or non-inflammatory lesions
- IGA score of “Almost Clear” corresponded to a few scattered comedones and a few small papules
- For severe acne patients there needed to be at least a 3 grade improvement

Narration

Treatment response was defined as the percent of subjects who were rated “Clear” and “Almost Clear” at week 12 with at least a 2-grade improvement based on the Investigator’s Global Assessment (IGA), and mean absolute change from baseline at week 12 in both inflammatory and non-inflammatory lesion counts. An IGA score of “Clear” corresponded to clear skin with no inflammatory or non-inflammatory lesions. An IGA score of “Almost Clear” corresponded to a few scattered comedones and a few small papules. Please note that for severe acne patients, there needed to be at least a 3-grade improvement on the IGA scale.

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Patient Characteristics

The screenshot shows a navigation bar at the top with 'LESSON 4' (highlighted in blue), 'Clinical Studies', and search/filter icons. Below this, three main categories are listed: 'Definition of Treatment Response', 'Patient Characteristics' (highlighted in red), and 'Study Results'. The 'Patient Characteristics' section contains the following text and bullet points:

Patient Characteristics

- 50% moderate (or IGA Grade 3); 50% severe (or IGA Grade 4) on the IGA scale
- Subjects had an average of 98 total lesions (inflammatory lesions: 38; non-inflammatory lesions: 60)
- Age range: 12 to 57 years
- Almost equal number of males (48%) and females (52%) enrolled

At the bottom of the slide, there is a Galderma logo, a progress bar indicating 'Screen 8 of 10', and navigation icons for back, forward, and refresh.

Narration

Patients were graded as “moderate” (or IGA Grade 3) or “severe” (or IGA Grade 4) on the IGA scale at baseline. Subjects had an average of 98 total lesions of which the mean number of inflammatory lesions was 38 and the mean number of non-inflammatory lesions was 60. Patients ranged in age from 12 to 57 years with an almost equal number of males and females enrolled.

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Study Results

The screenshot shows a navigation bar at the top with 'LESSON 4' selected, followed by 'Clinical Studies', a search icon, 'A-Z', a download icon, and 'iDASH'. Below this are three tabs: 'Definition of Treatment Response', 'Patient Characteristics', and 'Study Results' (which is highlighted in orange). The main content area is titled 'Study Results' and contains a table titled 'Clinical Efficacy of Epiduo Forte Gel at Week 12 in Subjects With Acne Vulgaris'. The table compares three groups: Epiduo Forte Gel (N = 217), Adapalene and Benzoyl Peroxide Gel, 0.1%/2.5% (N = 217)*, and Vehicle Gel (N = 69). The data shows significant improvements in both lesion types for the active gel groups compared to the vehicle control.

	Epiduo Forte Gel (N = 217)	Adapalene and Benzoyl Peroxide Gel, 0.1%/2.5% (N = 217)*	Vehicle Gel (N = 69)
IGA: Two Grade Improvement and "Clear" or "Almost Clear"	33.7%	27.3%	11.0%
Inflammatory Lesions: Mean Absolute (Percent) Reduction	27.8 (68.7%)	26.5 (69.3%)	13.2 (39.2%)
Non-inflammatory Lesions: Mean Absolute (Percent) Reduction	40.5 (68.3%)	40.0 (68.0%)	19.7 (37.4%)

*This study was not designed or powered to compare the efficacy of Epiduo Forte to the lower strength adapalene and benzoyl peroxide gel, 0.1%/2.5%, nor to compare the lower strength adapalene and benzoyl peroxide gel, 0.1%/2.5% to the vehicle control.

Narration

Epiduo Forte gel demonstrated superior efficacy results in the overall study population. At Week 12, 33.7% of subjects rated "clear" or "almost clear" with at least 2-grade improvement in the Epiduo Forte gel group compared to 11.0% for vehicle. The mean absolute percent reduction of inflammatory and non-inflammatory lesions was 68.7% and 68.3% in the Epiduo Forte gel group versus 39.2% and 37.4% for the placebo group. Also note in subjects with an IGA grade of 4 or severe, Epiduo Forte gel demonstrated superior efficacy compared to vehicle.

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How Supplied

LESSON 4 How Supplied ? A→Z ↓ iDASH



45-gram pump

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Narration

Epiduo Forte gel 0.3%/2.5% is white to very pale yellow in color and opaque in appearance, and is supplied as a 45-gram pump.

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Key Takeaways

The screenshot shows a mobile application interface. At the top, there is a navigation bar with icons for a menu (three horizontal lines), Lesson 4 (indicated by a blue circle with the number 4), Key Takeaways, a question mark, A to Z, a download arrow, and iDASH. The main content area contains a bulleted list of key takeaways about Epiduo and Epiduo Forte gel. At the bottom, there is a footer bar with the Galderma logo, a progress bar (labeled "Screen 10 of 10"), and navigation icons for back, forward, and refresh.

- Epiduo gel and Epiduo Forte gel have been demonstrated to be effective in the treatment of acne vulgaris
- Epiduo gel and Epiduo Forte gel are indicated for once-daily, topical application to areas affected by acne vulgaris
- Epiduo gel is indicated for patients age 9 and older
- The efficacy of Epiduo gel and Epiduo Forte gel was superior to that of vehicle gel
- In Study 1, 21.5% of patients who received Epiduo gel demonstrated a 2-grade improvement and clear or almost clear in IGA at week 12 compared with 12.2% of those who received adapalene 1% in vehicle gel and 12.1% who received benzoyl peroxide 2.5% in vehicle gel. Study 2 had similar results
- At week 12, 33.7% of patients who received Epiduo Forte gel demonstrated a 2-grade improvement and clear or almost clear in IGA compared with 11.0% who received vehicle gel only
- In subjects with an IGA grade of 4 or severe, Epiduo Forte gel demonstrated superior efficacy compared to vehicle

Narration

This is the end of Lesson 4. Take a few minutes to review the Key Takeaways from the module. When you are ready, tap the forward button to proceed to the flashcard activity and the assessment practice questions.

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eFlashcards

The image shows the eFlashcards interface. At the top, there is a header bar with a menu icon, 'LESSON 5' (highlighted in blue), the title 'eFlashcards', and icons for help, search, and iDASH. Below the header, a central instruction reads: 'Select a card to reveal a question. To check your answer, tap the Flip button.' Five cards are displayed in a grid:

- Rationale and Potential MOA of Adapalene-BPO
- Gollnick et al Study
- Pariser et al Study
- Pediatric Study
- Epiduo Gel and Epiduo Forte Gel

At the bottom of the screen, there is a footer bar with the Galderma logo, the text 'Screen 1 of 1', and 'For internal use only. Not to be used or distributed outside of Galderma.' followed by navigation icons: back, forward, refresh, and next.

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eFlashcard #1

The screenshot shows a digital flashcard titled "eFlashcard #1". The question asks: "Describe the rationale for adapalene-BPO as an acne treatment and its potential mechanism of action." A "Flip" button is visible at the bottom right. The interface includes a navigation bar with "LESSON 5" and "eFlashcards" buttons, and icons for search, sort, download, and iDASH.

eFlashcard #1

*Describe the rationale for
adapalene-BPO as an acne
treatment and its potential
mechanism of action.*

Flip

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Version 1 of 1

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of dermatology

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eFlashcard #1: Answer

Rationale	Adapalene	BPO
<ul style="list-style-type: none">Combination of adapalene and BPO work together to provide fast and long-lasting improvement of acneStrong anti-inflammatory, comedolytic, anti-comedogenic, and anti-bacterial componentsWorks against 3 out of 4 causative factors of acneEpiduo Forte gel developed with a higher strength of adapalene that offers providers another option for acne vulgaris patients	<ul style="list-style-type: none">Inhibits acne by:<ul style="list-style-type: none">Increasing cell turnover in the folliclesNormalizing keratinization of the epidermal cellsProducing anti-inflammatory action by inhibiting the cell-mediated inflammatory response	<ul style="list-style-type: none">Active against <i>P. acnes</i>Antimicrobial activity comes from oxidationCounteracts excessive sebum productionExfoliative and keratolytic properties on the epidermal layerDoes not induce bacterial resistance

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eFlashcard #2

The screenshot shows a digital flashcard titled "eFlashcard #2". The question is: "In the 12-week phase 3 study by Gollnick et al, what were the statistically significant efficacy results of the trial?". A "Flip" button is visible at the bottom right. The interface includes a navigation bar with icons for help, search, download, and iDASH, and a lesson progress indicator showing "LESSON 5" of "eFlashcards". A small Galderma logo is in the bottom left corner.

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eFlashcard #2: Answer

The screenshot shows a digital flashcard interface. At the top, it says "LESSON 5" and "eFlashcards". To the right are icons for help, A-Z, download, and iDASH. Below this is a list of bullet points and a table.

Bullet Points:

- Differences in success rate (defined as clear or almost clear) between adapalene/benzoyl peroxide combination therapy and all other treatments were statistically significant.
- Results showing the reduction in the inflammatory, non-inflammatory, and total lesion counts between adapalene/benzoyl peroxide combination therapy versus adapalene, BPO, and vehicle gel were statistically significant ($P < 0.001$).

Table:

	Treatment Group			
	Adapalene-BPO (n = 419)	Adapalene (n = 418)	BPO (n = 415)	Vehicle (n = 418)
Median percentage (%) change in lesion count				
Total	-65.4	-52.3	-48.2	-37.1
Inflammatory	-70.3	-57.1	-61.9	-45.5
Non-inflammatory	-62.2	-50.4	-48.8	-36.7
IGA: subjects with "clear", "almost clear", or "mild", (%)	75	63	59	53
Subject assessment (%): subjects with "complete improvement" or "marked improvement", (%)	50	44	39	29

Buttons:

- A red "X" button in the top right corner.
- A red "Flip" button on the right side of the table.
- Navigation icons at the bottom: back, forward, search, and exit.

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Screen 2 of 2

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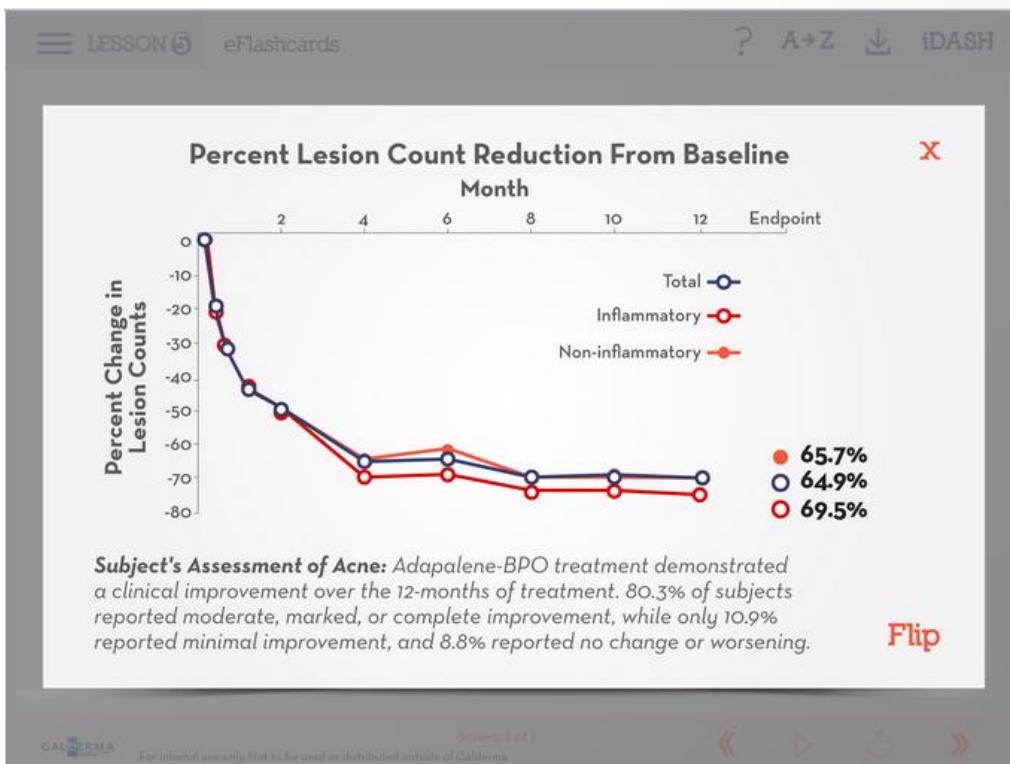
eFlashcard #3

The screenshot shows a mobile application interface for an eFlashcard. At the top, there is a navigation bar with icons for 'LESSON' (with a circular arrow), 'eFlashcards', a question mark, 'A-Z', a download icon, and 'iDASH'. The main content area has a light orange background and features the title 'eFlashcard #3' in large, bold, white font. Below the title is a question in black font: 'In the Phase III long-term safety and efficacy study by Eichenfield et al, what was the primary endpoint, and what were the results?'. In the bottom right corner of the card, there is a 'Flip' button. At the very bottom of the screen, there is a footer bar with the Galderma logo on the left, followed by the text 'For internal use only. Not to be used or distributed outside of Galderma.', and several navigation icons on the right.

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eFlashcard #3: Answer



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eFlashcard #4

The screenshot shows a digital flashcard titled "eFlashcard #4". The question asks: "What were the key findings in the 12-week pediatric study of adapalene 0.1% / benzoyl peroxide 2.5% gel vs vehicle cream?" A "Flip" button is visible at the bottom right. The interface includes a navigation bar with "LESSON 5", "eFlashcards", and icons for help, search, download, and iDASH.

LESSON 5 eFlashcards ? A→Z ⌂ iDASH

eFlashcard #4

What were the key findings in the 12-week pediatric study of adapalene 0.1% / benzoyl peroxide 2.5% gel vs vehicle cream?

Flip

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eFlashcard #4: Answer

The screenshot shows a digital flashcard interface. At the top, there are navigation icons: three horizontal lines (menu), 'LESSON 5' (with a circular arrow icon), 'eFlashcards', a question mark (?), 'A-Z' (alphabetical order), a download icon (down arrow), and 'iDASH'. In the center, a white rectangular area contains a bulleted list of five statements. In the top right corner of this area is a red 'X' icon. Below the list is a red 'Flip' button. At the bottom of the card, there is a small Galderma logo and the text 'For internal use only. Not to be used or distributed outside of Galderma.' To the right of this text are four small navigation icons: a double left arrow, a single left arrow, a single right arrow, and a double right arrow.

- The early treatment of acne is reasonable and well tolerated in children between the ages of 9 and 11
- Adapalene-BPO achieved a significantly higher treatment success compared to vehicle as early as week 4
- Adapalene-BPO was also significantly more effective in reducing both inflammatory and non-inflammatory lesions at week 12
- For total, inflammatory and non-inflammatory lesions, results were significantly superior for adapalene-BPO as early as week 1, and remained significant at all time points

Flip

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eFlashcard #5

The screenshot shows a digital flashcard titled "eFlashcard #5". The main question is: "What are the main differences in the indication and usages between Epiduo gel and Epiduo Forte gel?". A "Flip" button is located in the bottom right corner of the card. At the bottom of the screen, there is a footer bar with the Galderma logo, the text "For internal use only. Not to be used or distributed outside of Galderma.", and navigation icons.

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eFlashcard #5: Answer

	Epiduo Gel	Epiduo Forte Gel
Indication	Indicated for the topical treatment of acne vulgaris in patients 9 years of age and older	Indicated for the topical treatment of acne vulgaris
Dosage Forms and Strengths	0.1% adapalene, 2.5% benzoyl peroxide	0.3% adapalene, 2.5% benzoyl peroxide
Adverse Reactions	Dry skin, contact dermatitis, application site burning, application site irritation, and skin irritation	Skin irritation, eczema, atopic dermatitis, and skin burning sensation
Use in Specific Populations	Safety and efficacy in pediatric patients under the age of 9 have not been established	Safety and efficacy in pediatric patients under the age of 12 have not been established
Clinical Studies	<ul style="list-style-type: none">Majority of subjects had moderate acneStudy 1: 21.5% of patients who received Epiduo gel demonstrated a 2-grade improvement and clear or almost clear in IGA at week 12 compared with 12.2% of those who received adapalene 1% in vehicle gel and 12.1% who received benzoyl peroxide 2.5% in vehicle gel.Study 2 had similar results	<ul style="list-style-type: none">50% of subjects had moderate acne; 50% had severeAt week 12, 33.7% of patients who received Epiduo Forte gel demonstrated a 2-grade improvement and clear or almost clear in IGA compared with 11.0% who received vehicle gel onlyIn the severe subjects only (IGA Grade 4), Epiduo Forte gel was also shown to be superior to vehicle in the same endpoints

Flip

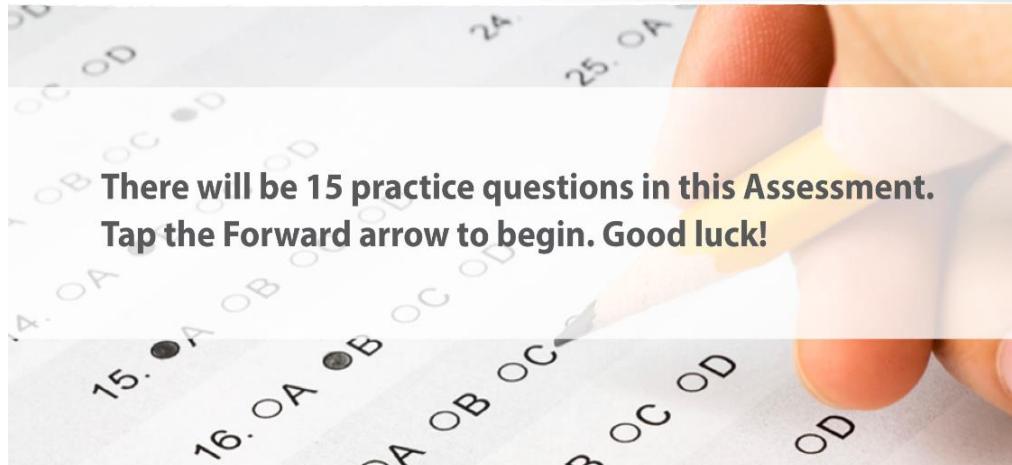
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Assessments

≡ LESSON 6 Assessment ? A→Z ⌂ iDASH



There will be 15 practice questions in this Assessment.
Tap the Forward arrow to begin. Good luck!

15. OA OB OC OD
16. OA OB OC OD

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Progress Check 1

≡ LESSON 6 Question 1 ? A→Z ↓ iDASH

Benzoyl peroxide is an antimicrobial, non-antibiotic agent. Which of the following statements is true?
(Check all that apply.)

- Penetrates skin into the blood stream in a significant amount
- Effective against *P. acnes*
- Modifies hormones
- No antibiotic resistance issues

Submit

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Progress Check 1: Answer

≡ LESSON 6 Question 1 ? A→Z ⌂ iDASH

Benzoyl peroxide is an antimicrobial, non-antibiotic agent. Which of the following statements is true?
(Check all that apply.)

- Penetrates skin into the blood stream in a significant amount
- Effective against *P. acnes*
- Modifies hormones
- No antibiotic resistance issues

Submit

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Progress Check 2

≡ LESSON 6 Question 2 ? A→Z ↓ iDASH

Identify the components of adapalene-BPO combination that work against the causative factors of acne. (Check all that apply.)

- Increased sebum production
- Anti-inflammatory
- Comedolytic
- Anti-comedogenic
- Antibacterial
- Antibiotic

Submit

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Progress Check 2: Answer

≡ LESSON 6 Question 2 ? A→Z ↓ iDASH

Identify the components of adapalene-BPO combination that work against the causative factors of acne. (Check all that apply.)

- Increased sebum production
- Anti-inflammatory
- Comedolytic
- Anti-comedogenic
- Antibacterial
- Antibiotic

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Progress Check 3

≡ LESSON ⑥ Question 3 ? A→Z ↓ iDASH

True or False: Epiduo gel contains 1 mg (0.1%) adapalene and 25 mg (2.5%) benzoyl peroxide in a white to very pale yellow, opaque gel. (Check all that apply.)

True
 False

Submit

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Progress Check 3: Answer

≡ LESSON 6 Question 3 ? A→Z ↓ iDASH

True or False: Epiduo gel contains 1 mg (0.1%) adapalene and 25 mg (2.5%) benzoyl peroxide in a white to very pale yellow, opaque gel. (Check all that apply.)

True
 False

Submit

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Progress Check 4

≡ LESSON 6 Question 4 ? A→Z ↓ iDASH

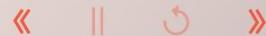
According to the Epiduo gel PI, which of the following statements are true? (Check all that apply.)

- Epiduo gel is indicated for the treatment of acne vulgaris in patients 9 years of age and older
- Epiduo gel is not for oral, ophthalmic, or intravaginal use
- Epiduo gel should be applied once daily to affected areas of face and/or trunk after washing
- Epiduo gel is contraindicated in patients with severe acne vulgaris

Submit



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Progress Check 4: Answer

≡ LESSON 6 Question 4 ? A→Z ⌂ iDASH

According to the Epiduo gel PI, which of the following statements are true? (Check all that apply.)

- Epiduo gel is indicated for the treatment of acne vulgaris in patients 9 years of age and older
- Epiduo gel is not for oral, ophthalmic, or intravaginal use
- Epiduo gel should be applied once daily to affected areas of face and/or trunk after washing
- Epiduo gel is contraindicated in patients with severe acne vulgaris

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Progress Check 5

≡ LESSON 6 Question 5 ? A→Z ↓ iDASH

Epiduo (adapalene and benzoyl peroxide) gel 0.1%/2.5% is supplied in which of the following:

- 45-gram tube and a 45-gram pump
- 45-gram tube and 15-gram pump
- 45-gram tube only
- 45-gram pump only

Submit

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Progress Check 5: Answer

≡ LESSON 6 Question 5 ? A→Z ⌂ iDASH

Epiduo (adapalene and benzoyl peroxide) gel 0.1%/2.5% is supplied in which of the following:

- 45-gram tube and a 45-gram pump
- 45-gram tube and 15-gram pump
- 45-gram tube only
- 45-gram pump only

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Progress Check 6

≡ LESSON 6 Question 6 ? A→Z ↓ iDASH

What were the most common drug-related adverse events reported in Epiduo gel clinical trials? (Check all that apply.)

Skin irritation Application site irritation
 Application site burning Eczema
 Contact dermatitis Atopic dermatitis
 Dry skin

Submit

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Progress Check 6: Answer

≡ LESSON 6 Question 6 ? A→Z ↓ iDASH

What were the most common drug-related adverse events reported in Epiduo gel clinical trials? (Check all that apply.)

Skin irritation Application site irritation
 Application site burning Eczema
 Contact dermatitis Atopic dermatitis
 Dry skin

Submit

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Progress Check 7

≡ LESSON 6 Question 7 ? A→Z ⌂ iDASH

What was the total lesion requirement to be included in the phase 3 study by Gollnick et al?

- 20 inflammatory and 20 non-inflammatory facial lesions
- >100 inflammatory/and or non-inflammatory facial lesions
- 20 to 50 inflammatory and 30 to 100 non-inflammatory facial lesions
- 20 to 100 inflammatory facial lesions only

Submit

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Progress Check 7: Answer

≡ LESSON 6 Question 7 ? A→Z ⌂ iDASH

What was the total lesion requirement to be included in the phase 3 study by Gollnick et al?

- 20 inflammatory and 20 non-inflammatory facial lesions
- >100 inflammatory/and or non-inflammatory facial lesions
- 20 to 50 inflammatory and 30 to 100 non-inflammatory facial lesions
- 20 to 100 inflammatory facial lesions only

Submit

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Progress Check 8

≡ LESSON 6 Question 8 ? A→Z ↓ iDASH

In the 12-week study by Gollnick et al, patients were randomized to receive which of the following?
(Check all that apply.)

- Adapalene/benzoyl peroxide combination therapy
- Adapalene monotherapy
- Benzoyl peroxide monotherapy
- Gel vehicle

Submit

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Progress Check 8: Answer

≡ LESSON 6 Question 8 ? A→Z ↓ iDASH

In the 12-week study by Gollnick et al, patients were randomized to receive which of the following?
(Check all that apply.)

- Adapalene/benzoyl peroxide combination therapy
- Adapalene monotherapy
- Benzoyl peroxide monotherapy
- Gel vehicle

Submit

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Progress Check 9

≡ LESSON 6 Question 9 ? A→Z ↓ iDASH

What percentage of patients using adapalene-BPO combination achieved IGA success rate at endpoint (week 12 - LOCF) in the study conducted by Gollnick et al?

- 21.8%
- 26.7%
- 37.9%
- 17.9%

Submit

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Progress Check 9: Answer

≡ LESSON 6 Question 9 ? A→Z ↓ iDASH

What percentage of patients using adapalene-BPO combination achieved IGA success rate at endpoint (week 12 - LOCF) in the study conducted by Gollnick et al?

- 21.8%
- 26.7%
- 37.9%
- 17.9%

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Progress Check 10

≡ LESSON 6 Question 10 ? A→Z ↓ iDASH

Which of the following statements are true about the long-term safety and efficacy study conducted by Parisner et al? (Check all that apply.)

- It was a multicenter, open-label, single-arm study conducted in the US for 12 months.
- Reductions in inflammatory, non-inflammatory, and total lesions were observed starting at week 8.
- Eighty percent of subjects reported moderate, marked, or complete improvement of their acne.
- The most adverse events and symptoms of skin irritation were mild to moderate, occurred early in the study, and decreased thereafter.

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Progress Check 10: Answer

≡ LESSON 6 Question 10 ? A→Z ↓ iDASH

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- Reductions in inflammatory, non-inflammatory, and total lesions were observed starting at week 8.
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Progress Check 11

≡ LESSON 6 Question 11 ? A→Z ↓ iDASH

What was the percentage reduction in inflammatory lesions in the adapalene-BPO group at week 12 in the pediatric study conducted by Eichenfield et al?

- 47.3%
- 51.8%
- 63.2%
- 70.6%

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Progress Check 11: Answer

≡ LESSON 6 Question 11 ? A→Z ⌂ iDASH

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- 51.8%
- 63.2%
- 70.6%

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Progress Check 12

≡ LESSON 6 Question 12 ? A→Z ↓ iDASH

What were the most common treatment-related AEs in the pediatric study? (Check all that apply.)

- Mild erythema
- Burning sensation
- Dryness
- Skin irritation

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Progress Check 12: Answer

≡ LESSON 6 Question 12 ? A→Z ↓ iDASH

What were the most common treatment-related AEs in the pediatric study? (Check all that apply.)

- Mild erythema
- Burning sensation
- Dryness
- Skin irritation

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Progress Check 13

≡ LESSON 6 Question 13 ? A→Z ↓ iDASH

At week 12, ____ of patients who received Epiduo Forte gel demonstrated 2-grade improvement and clear or almost clear based on IGA compared with ____ who received vehicle gel only.

- 10% and 23%
- 19.5 % and 12%
- 21.5% and 2%
- 33% and 11%

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Progress Check 13: Answer

≡ LESSON 6 Question 13 ? A→Z ↓ iDASH

At week 12, ____ of patients who received Epiduo Forte gel demonstrated 2-grade improvement and clear or almost clear based on IGA compared with ____ who received vehicle gel only.

- 10% and 23%
- 19.5 % and 12%
- 21.5% and 2%
- 33% and 11%

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Progress Check 14

≡ LESSON 6

Question 14

? A→Z ↓ iDASH

Complete the table summarizing the key differences between Epiduo gel and Epiduo Forte gel by dragging the answers from the Answer Pool to their correct placement in the table.

	Epiduo Gel	Epiduo Forte Gel
Indication		
Dosage Forms and Strengths		
Adverse Reactions	Dry skin, contact dermatitis, application site burning, application site irritation, and skin irritation	Skin irritation, eczema, atopic dermatitis, and skin burning sensation
Use in Specific Populations	Safety and efficacy in pediatric patients under the age of 9 have not been established	Safety and efficacy in pediatric patients under the age of 12 have not been established

Indicated for the topical treatment of acne vulgaris

0.3% adapalene, 2.5% benzoyl peroxide

0.1% adapalene, 2.5% benzoyl peroxide

Indicated for the topical treatment of acne vulgaris in patients 9 years of age and older

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Progress Check 14: Answer

≡ LESSON 6

Question 14

? A→Z ↓ iDASH

Complete the table summarizing the key differences between Epiduo gel and Epiduo Forte gel by dragging the answers from the Answer Pool to their correct placement in the table.

	Epiduo Gel	Epiduo Forte Gel
Indication	Indicated for the topical treatment of acne vulgaris in patients 9 years of age and older	Indicated for the topical treatment of acne vulgaris
Dosage Forms and Strengths	0.1% adapalene, 2.5% benzoyl peroxide	0.3% adapalene, 2.5% benzoyl peroxide
Adverse Reactions	Dry skin, contact dermatitis, application site burning, application site irritation, and skin irritation	Skin irritation, eczema, atopic dermatitis, and skin burning sensation
Use in Specific Populations	Safety and efficacy in pediatric patients under the age of 9 have not been established	Safety and efficacy in pediatric patients under the age of 12 have not been established

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Progress Check 15

≡ LESSON 6 Question 15 ? A→Z ↓ iDASH

True or False: In the Epiduo Forte gel clinical study, 50% of enrolled patients were graded as “moderate” (or 3) and 50% were graded as “severe” (or 4) at baseline on the IGA scale.

True
 False

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Progress Check 15: Answer

≡ LESSON 6 Question 15 ? A→Z ↓ iDASH

True or False: In the Epiduo Forte gel clinical study, 50% of enrolled patients were graded as “moderate” (or 3) and 50% were graded as “severe” (or 4) at baseline on the IGA scale.

True
 False

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Glossary

Term	Definition
concomitant	accompanying, especially in a subordinate or incidental way
contact dermatitis	inflammation of the skin due to contact with allergens or an irritating substance
cutaneous	of, relating to, or affecting the skin
cytosolic	the fluid portion of the cytoplasm exclusive of organelles and membranes
desquamating	process of shedding of the cuticle in scales or of the outer layer of any surface
eczema	an inflammatory condition of the skin characterized by redness, itching, and oozing vesicular lesions which become scaly, crusted, or hardened
erythema	abnormal redness of the skin cause by dilation of blood vessels and capillaries near the skin's surface
hyperpigmentation	increased pigmentation
keratolytic	ability to separate or loosen the horny layer of the epidermis
last observation carried forward	the last measured outcome of a study subject; ie, if patient drops out of a study before it ends, then his or her last observed score is used for all subsequent observation points. This technique assumes patients improve gradually from the start of the study until the end, so that carrying forward a value is a conservative estimate of how well treatment would have done if the subject had remained in the study
pregnancy category	an assessment of the risk of fetal injury due to a drug
retinoid	a class of keratolytic drugs, that has anti-comedogenic activity, derived from retinoic acid and used for treatment of severe acne and psoriasis
tolerability	the capacity to endure exposure to a large concentration or quantity of a substance (such as a drug, food, or poison)

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