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2. Roflumilast

Roflumilast Topical

Pronunciation: *zor-EEV***Brand name:** [Zoryve](#)**Dosage form:** cream (0.15%), cream (0.3%), foam (0.3%)**Drug class:** [Selective phosphodiesterase-4 inhibitors](#)Medically reviewed by [Melisa Puckey, BPharm](#). Last updated on Feb 26, 2025.[Uses](#) [Side effects](#) [Warnings](#) [Before taking](#) [Dosage](#) [Interactions](#)

What is roflumilast?

Roflumilast ([Zoryve](#)) is a steroid-free, once-daily topical cream or foam used to treat [plaque psoriasis](#), [atopic dermatitis](#), and [seborrheic dermatitis](#) to help reduce itching, and inflammation and improve skin symptoms. Roflumilast cream is used for plaque psoriasis and atopic dermatitis, it absorbs quickly and can be applied to sensitive areas including the face, skin folds, and genitalia. Roflumilast foam is used for seborrheic dermatitis and can be applied to affected skin areas including hairy areas and scalp.

Roflumilast is a **phosphodiesterase 4 inhibitor**.

Roflumilast brand name is Zoryve Cream and Zoryve Foam. Roflumilast is also available as a tablet for COPD (chronic obstructive pulmonary disease) under the brand name [Daliresp](#).

Roflumilast works (mechanism of action) by inhibiting PDE4, an enzyme that plays an important role in controlling inflammation and immune responses in the body. By inhibiting PDE-4 (Phosphodiesterase-4) roflumilast helps to reduce redness, itch, and scaling to improve skin symptoms.

What are roflumilast cream and roflumilast foam used for?

Roflumilast FDA approval is to treat:

- **Plaque psoriasis (0.3% cream)** in patients 6 years and older.
- **Atopic dermatitis (0.15% cream)** in patients 6 years and older.
- **Seborrheic dermatitis (0.3% foam)** in patients 9 years and older.

Roflumilast Side Effects

Common roflumilast side effects (cream 0.3% – psoriasis)

- [Diarrhea](#) (3.1%)

- [Headache](#) (2.4%)
- [Insomnia](#) (1.4%)
- Nausea (1.2%)
- Application site pain(1.0%)
- [Upper respiratory infections](#) (1.0%)
- [Urinary tract infections](#) (1.0%)

Common roflumilast side effects (cream 0.15% – atopic dermatitis)

- Headache (2.9%)
- [Nausea](#) (1.9%)
- Application site pain(1.5%)
- Diarrhea (1.5%)
- Vomiting (1.5%)

Common side effects (foam 0.3% – seborrheic dermatitis)

- Nausea (1.3%)
- Headache (1.1%)
- Cold symptoms (1.5%)

These are not all of the possible side effects. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088. You may also report side effects to Arcutis Biotherapeutics, Inc. by calling 1-844-692-6729..

 [Roflumilast topical side effects](#) (more detail)

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How well does roflumilast work?

Plaque Psoriasis – DERMIS-1 Study ([NCT04211363](#)) and DERMIS-2 ([NCT04211389](#))

- **41.5% of roflumilast patients** had **clear or almost clear skin** in **8 weeks** (vs. 5.8% on placebo). Measured using Investigator's Global Assessment (IGA) score
- **67.5% of patients** reported a **4-point reduction in itch** by **week 8** (measured using the Worst Itch-Numeric Rating Scale (WI-NRS) score)

Atopic Dermatitis – INTEGUMENT-1 ([NCT04773587](#))

- **33.6% of roflumilast patients** had a **successful improvement of itch** within **4 weeks** (measured using the WI-NRS score)
- **Itch relief started within 24 hours** of application.

Seborrheic Dermatitis – STRATUM [[NCT04973228](#)]

- **79.5% of roflumilast patients** had **clear or almost clear skin** in **8 weeks** vs. 58% placebo (measured using IGA score)

- **50.7% achieved complete clearance** by week 8.

Warning

Do not use roflumilast cream or foam if you have certain liver problems, including moderate to severe liver impairment.

Roflumilast foam is flammable. Avoid fire, flame, and smoking when applying and right after you apply it.

Before using this medicine

Before you start treatment, tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems.

Pregnancy

Tell your healthcare provider if you are pregnant or plan to become pregnant, as it is not known if roflumilast will harm your unborn baby.

Breastfeeding

Tell your healthcare provider if you are breastfeeding or planning to breastfeed. Talk to your healthcare provider about the best way to feed your baby during treatment with this cream.

Breastfeeding women using the cream or foam should use it on the smallest area of the skin and for the shortest time needed. Do not apply this cream or foam directly to the nipple or areola if you are breastfeeding to avoid contact with the product with your baby.

 [Roflumilast topical pregnancy and breastfeeding warnings](#) (more detail)

How should I use roflumilast?

Roflumilast Cream

1. Apply a thin layer to affected areas once daily.
2. Rub in completely until it disappears.
3. Wash hands after application (unless treating hands).

Roflumilast Foam

1. Apply a thin layer to affected areas once daily.
2. Shake well before use.
3. Turn the can upside down and dispense it into your hand.
4. Apply to dry skin and rub in completely.
5. Wash hands after application.

Roflumilast dosing information

Roflumilast Cream Dose for Atopic Dermatitis or Plaque Psoriasis: Apply once daily to affected areas

Roflumilast Foam Dose for Seborrheic Dermatitis: Apply once daily to affected areas

General dosing information: For topical use only. Not for ophthalmic, oral, or intravaginal use.

 [Detailed Roflumilast topical dosage information](#)

What other drugs will affect this medicine?

Tell your healthcare provider about the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Using roflumilast cream or foam with medicines that are systemic CYP3A4 inhibitors or dual inhibitors that inhibit both CYP3A4 and CYP1A2 simultaneously may increase the active ingredient roflumilast systemic exposure and may increase side effects. It is important to weigh up the potential for increased adverse reactions against benefit if these products are used together with Roflumilast cream or foam.

Using roflumilast cream with oral contraceptives containing gestodene and ethinyl estradiol may increase roflumilast systemic exposure and may result in increased side effects. The risk of such concurrent use should be weighed carefully against the benefit.

This list is not complete. Not all possible drug interactions are listed here.

 [Roflumilast topical drug interactions](#) (more detail)

Does roflumilast topical interact with my other drugs?

Enter medications to view a detailed interaction report using our [Drug Interaction Checker](#).

roflumilast topical

+

Enter a drug name

Add

Roflumilast Package Insert

Review the [Zoryve Cream Package Insert](#) or [Zoryve Foam Package Insert](#) for more detailed information about this medicine. Discuss any medical questions you have with your doctor or other health care provider. This is not all the information you need to know about this medicine for safe and effective use, and it does not take the place of talking to your doctor about your treatment.

Storage

Cream storage

- Store at room temperature from 68°F to 77°F (20°C to 25°C).

Foam storage

- Store at room temperature between 68°F to 77°F (20°C to 25°C).
- This foam is flammable. Keep away from heat and flame.
- The contents foam are under pressure. Do not puncture or burn the can. Do not expose to heat or store at temperatures above 120°F (49°C).
- Do not freeze. Store the can upright.

Ingredients

Active ingredient: roflumilast

Zoryve Cream inactive ingredients: cetareth-10 phosphate, cetearyl phosphate, cetostearyl alcohol, diethylene glycol monoethyl ether, hexylene glycol, isopropyl palmitate, methylparaben, propylparaben, purified water, sodium hydroxide, and white petrolatum. Hydrochloric acid may have been added to adjust pH.

Zoryve Foam inactive ingredients: cetareth-10 phosphate, cetearyl phosphate, cetostearyl alcohol, diethylene glycol monoethyl ether, hexylene glycol, isopropyl palmitate, methylparaben, propylparaben, purified water, sodium hydroxide, and white petrolatum. Hydrochloric acid may have been added to adjust pH. Propellants: butane, isobutane, and propane.

Company

Zoryve Arcutis Biotherapeutics, Inc. Westlake Village, CA 91361.

References

1. [Roflumilast Cream, 0.15%, for Atopic Dermatitis in Adults and Children: INTEGUMENT-1 and INTEGUMENT-2 Randomized Clinical Trials](#)
2. [Zoryve Cream Product Label - FDA](#)
3. [Zoryve Foam Product Label FDA](#)
4. [Efficacy and safety of roflumilast foam 0.3% in patients with seborrheic dermatitis in a phase 3 trial](#)
5. [Long-term safety and effectiveness of roflumilast cream 0.3% in adults with chronic plaque psoriasis: A 52-week, phase 2, open-label trial](#)
6. [Effect of Roflumilast Cream vs Vehicle Cream on Chronic Plaque Psoriasis](#)

More about roflumilast topical

- [Check interactions](#)
- [Compare alternatives](#)
- [Reviews \(49\)](#)
- [Side effects](#)
- [Dosage information](#)

- [During pregnancy](#)
- [Drug class: selective phosphodiesterase-4 inhibitors](#)
- [Breastfeeding](#)
- [En español](#)

Patient resources

- [Roflumilast \(Topical application\) advanced reading](#)

Other brands

[Zoryve](#)

Professional resources

- [Roflumilast \(Topical\) monograph](#)

Other brands

[Zoryve](#), [Zoryve Foam](#)

Related treatment guides

- [Seborrheic Dermatitis](#)
- [Plaque Psoriasis](#)

Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

[Medical Disclaimer](#)

DRUG STATUS

Availability

Rx Prescription only


[Pregnancy & Lactation](#)

 Risk data available

CSA Schedule*

N/A Not a controlled drug

Approval History

 Drug history at FDA



User Reviews & Ratings

8.6 / 10

[49 Reviews](#)

Images

[Zoryve Cream \(roflumilast\) multiple strengths](#)



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