SUN PHARMA

HALOG®
(Halcinonide, USP) 0.1%

Ultravate® Lotion
(halobetasol propionate, 0.05%)

Helping patients access quality brands

Patient Information

- **To activate this card, visit www.activatethecard.com/7378**
- **Present card to pharmacy**
- **Reusable card. Retain card for future use.**
- **Call 1-855-820-9077**

The LOYALTYSCRIPT® Card is not valid for use with any other prescription drug discount or cash cards for HALOG Solution, HALOG Cream, HALOG Ointment and ULTRAVATE Lotion. Claims submitted utilizing the program are subject to audit or validation. The LOYALTYSCRIPT® Card is not valid for use by HALOG Cream patients who reside in the State of California or the Commonwealth of Massachusetts.

Eligible Commercially insured patients:

Pay as little as $0 per product per Prescription*

Please see program terms and conditions on reverse side. Additional restrictions may apply.

Prescriptions that may be reimbursed under a federal or state healthcare program (including Medicaid and Medicare) are not eligible under this program. Based on when insurance and shipping information are received. Manufacturer reserves the right to change the Co-Pay program rules at any time.

Eligibility: Commercially Insured patients ONLY
BILL PRIMARY INSURANCE FIRST

RxBIN: **610524**
RxPCN: **Loyalty**
RxGRP: **50777378**
ISSUER: **(80840)**

ID: XXXXXXXXX

Powered By: MCKESSON

Not valid with any other offer.

To the Patient:

You must present this card to the pharmacist along with your prescription to participate in this program. If you have any questions regarding your eligibility or benefits, or if you wish to discontinue your participation, call the Sun Pharma program at 1-855-820-9077 (8:00 AM-8:00 PM EST, Monday-Friday). When you use this card, you are certifying that you understand the program rules, regulations, and terms and conditions. You are not eligible if prescriptions are paid by any state or other federally funded programs, including, but not limited to Medicare or Medicaid, Medigap, VA or DOD or TriCare, or where prohibited by law; and you will otherwise comply with the terms above.

To the Pharmacist:

When you use this card, you are certifying that you have not submitted and will not submit a claim for reimbursement under any federal, state or other governmental programs for this prescription.

- Submit transaction to McKesson Corporation using BIN #610524
- If primary commercial prescription insurance exists, input card information as secondary coverage and transmit using the COB segment of the NCPDP transaction. Applicable discounts will be displayed in the transaction response.
- The LoyaltyScript® Card is not valid for use with any other prescription drug discount or cash cards for ULTRAVATE® Lotion, HALOG®. Claims submitted utilizing the program are subject to audit or validation.
- Acceptance of this card and your submission of claims for the Sun Pharma program are subject to the LoyaltyScript® program Terms and Conditions posted at www.mckesson.com/mprstnc
- Patient is not eligible if prescriptions are paid in part or full by any state or federally funded programs, including but not limited to Medicare or Medicaid, Medigap, VA, DOD or TriCare and where prohibited by law.
- For questions regarding setup, claim transmission, patient eligibility or other issues, call the LoyaltyScript® for Sun Pharma program at 1-855-820-9077 (8:00 AM-8:00 PM EST, Monday-Friday). Sun Pharma reserves the right to rescind, revoke or amend this offer at any time.

If you experience any Adverse Events you are encouraged to report them. To report Adverse Events with ULTRAVATE, or HALOG call 1-800-406-7984. You can also report to the FDA at 1-800-FDA-1088 or http://www.fda.gov/medwatch.

PM-US-HLG-0085 07/2020

SUN PHARMA

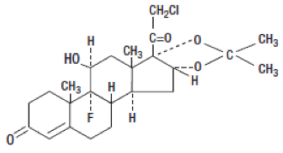
HALOG® SOLUTION
(Halcinonide Topical Solution, USP) 0.1 %

For Topical Use Only. Not For Ophthalmic Use.

Rx Only

PPK-8860-0
29

DESCRIPTION
The topical corticosteroids constitute a class of primarily synthetic steroids used as anti-inflammatory and antipruritic agents. The steroids in this class include halcinonide. Halcinonide is designated chemically as 21-Chloro-9-fluoro-11β,16α, 17-trihydroxypregn-4-ene-3,20-dione cyclic 16,17-acetal with acetone. Structural formula:



$C_{24}H_{32}ClFO_5$, MW 454.96, CAS-3093-35-4

Each mL of 0.1% HALOG SOLUTION (Halcinonide Topical Solution, USP) contains 1 mg halcinonide, edetate disodium, polyethylene glycol 300, and purified water with butylated hydroxytoluene as an antioxidant.

CLINICAL PHARMACOLOGY
Topical corticosteroids share anti-inflammatory, antipruritic and vasoconstrictive actions.

The mechanism of anti-inflammatory activity of the topical corticosteroids is unclear. Various laboratory methods, including vasoconstrictor assays, are used to compare and predict potencies and/or clinical efficacies of the topical corticosteroids. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

Pharmacokinetics
The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.

Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption.

Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids. Thus, occlusive dressings may be a valuable therapeutic adjunct for treatment of resistant dermatoses **(see DOSAGE AND ADMINISTRATION).**

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

INDICATIONS AND USAGE
HALOG SOLUTION (Halcinonide Topical Solution, USP) 0.1% is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

CONTRAINDICATIONS
Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparations.

PRECAUTIONS
General
Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings.

Therefore, patients receiving a large dose of any potent topical steroid applied to a large surface area or under an occlusive dressing should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests, and for impairment of thermal homeostasis. If HPA axis suppression or elevation of the body temperature occurs, an attempt should be made to withdraw the drug, to reduce the frequency of application, substitute a less potent steroid, or use a sequential approach when utilizing the occlusive technique.

Recovery of HPA axis function and thermal homeostasis are generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.

Occasionally, a patient may develop a sensitivity reaction to a particular occlusive dressing material or adhesive and a substitute material may be necessary.

Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity **(see PRECAUTIONS: Pediatric Use).**

If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted.

In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

This preparation is not for ophthalmic use.

Information for the Patient
Patients using topical corticosteroids should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for dermatologic use only. Avoid contact with the eyes.
2. Patients should be advised not to use this medication for any disorder other than for which it was prescribed.
3. The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by the physician.
4. Patients should report any signs of local adverse reactions especially under occlusive dressing.
5. Parents of pediatric patients should be advised not to use tight-fitting diapers or plastic pants on a child being treated in the diaper area, as these garments may constitute occlusive dressings.

Laboratory Tests
A urinary free cortisol test and ACTH stimulation test may be helpful in evaluating HPA axis suppression.

Carcinogenesis, Mutagenesis, and Impairment of Fertility
Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids.

Studies to determine mutagenicity with prednisolone and hydrocortisone showed negative results.

Pregnancy
Teratogenic Effects
Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

Nursing Mothers
It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.

Pediatric Use
Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio.

HPA axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.

Geriatric Use
Clinical studies of 0.1% HALOG SOLUTION (Halcinonide Topical Solution, USP) did not include sufficient numbers of patients aged 65 years and over to determine whether they respond differently from younger patients. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range.

ADVERSE REACTIONS
The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings (reactions are listed in an approximate decreasing order of occurrence): burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, and miliaria.

OVERDOSAGE
Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects **(see PRECAUTIONS: General).**

DOSAGE AND ADMINISTRATION
Apply HALOG SOLUTION (Halcinonide Topical Solution, USP) 0.1% to the affected area two to three times daily.

Occlusive Dressing Technique
Occlusive dressings may be used for the management of psoriasis or other recalcitrant conditions. Apply the solution to the lesion, cover with a pliable nonporous film, and seal the edges. If needed, additional moisture may be provided by covering the lesion with a dampened clean cotton cloth before the nonporous film is applied or by briefly wetting the affected area with water immediately prior to applying the medication. The frequency of changing dressings is best determined on an individual basis. It may be convenient to apply HALOG SOLUTION under an occlusive dressing in the evening and to remove the dressing in the morning (i.e., 12-hour occlusion). When utilizing the 12-hour occlusion regimen, additional solution should be applied, without occlusion, during the day. Reapplication is essential at each dressing change.

If an infection develops, the use of occlusive dressings should be discontinued and appropriate antimicrobial therapy instituted.

HOW SUPPLIED
HALOG® SOLUTION (Halcinonide Topical Solution, USP) 0.1% is supplied in plastic squeeze bottles containing, 60 mL (NDC 10631-095-20), and 120 mL (NDC 10631-095-10) of solution.

Storage
Store at room temperature; avoid freezing and temperatures above 104° F.

To report SUSPECTED ADVERSE REACTIONS, contact Sun Pharmaceutical Industries, Inc. at 1-800-406-7984 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Distributed by:
Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512

SUN PHARMA

Revised July 2019

PPK-8860-0

HALOG® OINTMENT
(Halcinonide Ointment, USP) 0.1%

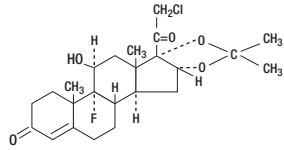
Rx only

FOR TOPICAL USE ONLY.
NOT FOR OPHTHALMIC, ORAL, OR INTRAVAGINAL USE.

SX

DESCRIPTION

The topical corticosteroids constitute a class of primarily synthetic steroids used as anti-inflammatory and antipruritic agents. The steroids in this class include halcinonide. Halcinonide is designated chemically as 21-Chloro-9-fluoro-11β,16α, 17-trihydroxypregn-4-ene-3,20-dione cyclic 16,17-acetal with acetone. Graphic formula:



$C_{24}H_{32}ClFO_5$, MW 454.96, CAS-3093-35-4

Each gram of 0.1% HALOG OINTMENT (Halcinonide Ointment, USP) contains 1 mg halcinonide in Plastibase® (Plasticized Hydrocarbon Gel), a mineral oil and polyethylene gel base, polyethylene glycol 300, polyethylene glycol 400, polyethylene glycol 1450, and polyethylene glycol 6000 distearate with butylated hydroxytoluene as an antioxidant.

CLINICAL PHARMACOLOGY

Topical corticosteroids share anti-inflammatory, antipruritic and vasoconstrictive actions.

The mechanism of anti-inflammatory activity of the topical corticosteroids is unclear. Various laboratory methods, including vasoconstrictor assays, are used to compare and predict potencies and/or clinical efficacies of the topical corticosteroids. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

Pharmacokinetics

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.

Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids. Thus, occlusive dressings may be a valuable therapeutic adjunct for treatment of resistant dermatoses (see **DOSAGE AND ADMINISTRATION**).

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

INDICATIONS AND USAGE

HALOG OINTMENT (Halcinonide Ointment, USP) 0.1% is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

CONTRAINDICATIONS

Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparations.

PRECAUTIONS

General

Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings.

Therefore, patients receiving a large dose of any potent topical steroid applied to a large surface area or under an occlusive dressing should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests, and for impairment of thermal homeostasis. If HPA axis suppression or elevation of the body temperature occurs, an attempt should be made to withdraw the drug, to reduce the frequency of application, substitute a less potent steroid, or use a sequential approach when utilizing the occlusive technique.

Recovery of HPA axis function and thermal homeostasis are generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids. Occasionally, a patient may develop a sensitivity reaction to a particular occlusive dressing material or adhesive and a substitute material may be necessary.

Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity (see **PRECAUTIONS: Pediatric Use**).

If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted.

In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

This preparation is not for ophthalmic, oral, or intravaginal use.

Information for the Patient

Patients using topical corticosteroids should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for dermatologic use only. Avoid contact with the eyes.
2. Patients should be advised not to use this medication for any disorder other than for which it was prescribed.
3. The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by the physician.
4. Patients should report any signs of local adverse reactions especially under occlusive dressing.
5. Parents of pediatric patients should be advised not to use tight-fitting diapers or plastic pants on a child being treated in the diaper area, as these garments may constitute occlusive dressings.

XS

Laboratory Tests
A urinary free cortisol test and ACTH stimulation test may be helpful in evaluating HPA axis suppression.

Carcinogenesis, Mutagenesis, and Impairment of Fertility
Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids.
Studies to determine mutagenicity with prednisolone and hydrocortisone showed negative results.

Pregnancy
Teratogenic Effects
Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

Nursing Mothers
It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities **not** likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.

Pediatric Use
Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio.
HPA axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.
Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.

Geriatric Use
Clinical studies of 0.1% HALOG OINTMENT did not include sufficient numbers of patients aged 65 years and over to determine whether they respond differently from younger patients. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range.

ADVERSE REACTIONS
The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings (reactions are listed in an approximate decreasing order of occurrence): burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, and miliaria.

OVERDOSAGE
Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (see **PRECAUTIONS: Genera**l).

DOSAGE AND ADMINISTRATION
Apply a thin film of 0.1% HALOG OINTMENT (Halcinonide Ointment, USP) to the affected area two to three times daily.

Occlusive Dressing Technique
Occlusive dressings may be used for the management of psoriasis or other recalcitrant conditions. Apply a thin film of ointment to the lesion, cover with a pliable nonporous film, and seal the edges. If needed, additional moisture may be provided by covering the lesion with a dampened clean cotton cloth before the nonporous film is applied or by briefly wetting the affected area with water immediately prior to applying the medication. The frequency of changing dressings is best determined on an individual basis. It may be convenient to apply HALOG OINTMENT under an occlusive dressing in the evening and to remove the dressing in the morning (i.e., 12-hour occlusion). When utilizing the 12-hour occlusion regimen, additional ointment should be applied, without occlusion, during the day. Reapplication is essential at each dressing change.
If an infection develops, the use of occlusive dressings should be discontinued and appropriate antimicrobial therapy instituted.

HOW SUPPLIED
HALOG® OINTMENT (Halcinonide Ointment, USP) 0.1% is translucent white to off-white, smooth, soft homogeneous ointment type material, essentially free of foreign matter and is supplied as:

NDC 10631-096-30	Tube containing 60 g
NDC 10631-096-71	240 g (4 Tubes of 60 g)

Storage
Store at room temperature; avoid excessive heat (104º F).

To report SUSPECTED ADVERSE REACTIONS, contact the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Manufactured by:
DPT Laboratories Inc.
San Antonio, TX 78215

Distributed by:
Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512

SUN
PHARMA

141012

Revised October 2018

HALOG®
(Halcinonide Cream, USP) 0.1%

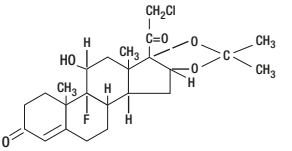
Rx only

FOR TOPICAL USE ONLY.
NOT FOR OPHTHALMIC, ORAL, OR INTRAVAGINAL USE.

XM

DESCRIPTION

The topical corticosteroids constitute a class of primarily synthetic steroids used as anti-inflammatory and antipruritic agents. The steroids in this class include halcinonide. Halcinonide, USP is designated chemically as 21-Chloro-9-fluoro-11β,16α, 17-trihydroxypregn-4-ene-3,20-dione cyclic 16,17-acetal with acetone. Graphic formula:



$C_{24}H_{32}ClFO_5$, MW 454.96, CAS-3093-35-4

Each gram of 0.1% HALOG (Halcinonide Cream, USP) contains 1 mg halcinonide, USP in a specially formulated cream base consisting of cetyl alcohol, dimethicone 350, glyceryl monostearate, isopropyl palmitate, polysorbate 60, propylene glycol, purified water, and titanium dioxide.

CLINICAL PHARMACOLOGY

Topical corticosteroids share anti-inflammatory, antipruritic and vasoconstrictive actions.

The mechanism of anti-inflammatory activity of the topical corticosteroids is unclear. Various laboratory methods, including vasoconstrictor assays, are used to compare and predict potencies and/or clinical efficacies of the topical corticosteroids. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

Pharmacokinetics

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.

Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids. Thus, occlusive dressings may be a valuable therapeutic adjunct for treatment of resistant dermatoses (see **DOSAGE AND ADMINISTRATION**).

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

INDICATIONS AND USAGE

HALOG (Halcinonide Cream, USP) 0.1% is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

CONTRAINDICATIONS

Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparations.

PRECAUTIONS

General

Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings.

Therefore, patients receiving a large dose of any potent topical steroid applied to a large surface area or under an occlusive dressing should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests, and for impairment of thermal homeostasis. If HPA axis suppression or elevation of the body temperature occurs, an attempt should be made to withdraw the drug, to reduce the frequency of application, substitute a less potent steroid, or use a sequential approach when utilizing the occlusive technique.

Recovery of HPA axis function and thermal homeostasis are generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids. Occasionally, a patient may develop a sensitivity reaction to a particular occlusive dressing material or adhesive and a substitute material may be necessary.

Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity (see **PRECAUTIONS: Pediatric Use**).

If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted.

In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

This preparation is not for ophthalmic, oral, or intravaginal use.

Information for the Patient

Patients using topical corticosteroids should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for dermatologic use only. Avoid contact with the eyes.
2. Patients should be advised not to use this medication for any disorder other than for which it was prescribed.
3. The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by the physician.
4. Patients should report any signs of local adverse reactions especially under occlusive dressing.
5. Parents of pediatric patients should be advised not to use tight-fitting diapers or plastic pants on a child being treated in the diaper area, as these garments may constitute occlusive dressings.

XM

Laboratory Tests
A urinary free cortisol test and ACTH stimulation test may be helpful in evaluating HPA axis suppression.

Carcinogenesis, Mutagenesis, and Impairment of Fertility
Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids.
Studies to determine mutagenicity with prednisolone and hydrocortisone showed negative results.

Pregnancy
Teratogenic Effects
Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

Nursing Mothers
It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities **not** likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.

Pediatric Use
Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio.
HPA axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.
Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.

Geriatric Use
Of approximately 3000 patients included in clinical studies of 0.1% HALOG CREAM, 14% were 60 years or older, while 4% were 70 years or older. No overall differences in safety were observed between these patients and younger patients. Efficacy data have not been evaluated for differences between elderly and younger patients. Other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

ADVERSE REACTIONS
The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings (reactions are listed in an approximate decreasing order of occurrence): burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, and miliaria.

OVERDOSAGE
Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (see **PRECAUTIONS: General**).

DOSAGE AND ADMINISTRATION
Apply the 0.1% HALOG (Halcinonide Cream, USP) to the affected area two to three times daily. Rub in gently.

Occlusive Dressing Technique
Occlusive dressings may be used for the management of psoriasis or other recalcitrant conditions. Gently rub a small amount of cream into the lesion until it disappears. Reapply the preparation leaving a thin coating on the lesion, cover with a pliable nonporous film, and seal the edges. If needed, additional moisture may be provided by covering the lesion with a dampened clean cotton cloth before the nonporous film is applied or by briefly wetting the affected area with water immediately prior to applying the medication. The frequency of changing dressings is best determined on an individual basis. It may be convenient to apply HALOG under an occlusive dressing in the evening and to remove the dressing in the morning (i.e., 12-hour occlusion). When utilizing the 12-hour occlusion regimen, additional cream should be applied, without occlusion, during the day. Reapplication is essential at each dressing change.
If an infection develops, the use of occlusive dressings should be discontinued and appropriate antimicrobial therapy instituted.

HOW SUPPLIED
HALOG® (Halcinonide Cream, USP) 0.1% is smooth, soft homogeneous white to off-white cream, essentially free of foreign matter and is supplied as:

NDC 10631-094-30	Tube containing 60 g
NDC 10631-094-76	Jar containing 216 g
NDC 10631-094-71	Carton containing 240 g (4 tubes of 60g)

Storage
Store at room temperature; avoid excessive heat (104° F).

To report SUSPECTED ADVERSE REACTIONS, contact the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Manufactured by:
DPT Laboratories Inc.
San Antonio, TX 78215

Distributed by:
Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512

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Revised May 2018

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ULTRAVATE® lotion safely and effectively. See full prescribing information for ULTRAVATE lotion.

ULTRAVATE (halobetasol propionate) lotion
Initial U.S. Approval: 1990

INDICATIONS AND USAGE

ULTRAVATE lotion is a corticosteroid indicated for the topical treatment of plaque psoriasis in patients eighteen (18) years of age and older. (1)

DOSAGE AND ADMINISTRATION

- Apply a thin layer to the affected areas twice daily. (2)
- Limit use to 50 g/week. (2)
- Discontinue ULTRAVATE lotion when control is achieved. (2)
- If no improvement is seen within 2 weeks, reassess diagnosis. (2)
- Treatment beyond 2 consecutive weeks is not recommended. (2)
- Do not use with occlusive dressings unless directed by a physician. (2)
- Avoid use on the face, scalp, groin, or axillae. (2)
- ULTRAVATE lotion is not for ophthalmic, oral, or intravaginal use. (2)

DOSAGE FORMS AND STRENGTHS

Lotion: 0.05% (0.5 mg/g). (3)

CONTRAINDICATIONS

- None. (4)

WARNINGS AND PRECAUTIONS

- Reversible hypothalamic-pituitary-adrenal (HPA) axis suppression may occur, with the potential for glucocorticosteroid insufficiency during or after treatment. (5.1)
- Systemic effects of topical corticosteroids may also include Cushing's syndrome, hyperglycemia, and glucosuria. (5.1)
- Systemic absorption may require evaluation for HPA axis suppression. (5.1)
- Use of potent corticosteroids on large areas, for prolonged durations, under occlusive dressings, or on an altered skin barrier may increase systemic exposure. (5.1)
- Children may be more susceptible to systemic toxicity when treated with topical corticosteroids. (5.1, 8.4)
- Local adverse reactions with topical steroids may include atrophy, striae, irritation, acneiform eruptions, hypopigmentation, and allergic contact dermatitis. Adverse reactions may be more likely to occur with occlusive use or more potent corticosteroids. (5.2, 5.4)
- Initiate appropriate therapy if concomitant skin infections develop. (5.3)

ADVERSE REACTIONS

The most commonly reported adverse reactions (≥1%) are telangiectasia, application site atrophy, and headache. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Drug Safety at 1-800-406-7984 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 11/2017

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1. INDICATIONS AND USAGE

ULTRAVATE lotion is indicated for the topical treatment of plaque psoriasis in patients eighteen (18) years of age and older.

2. DOSAGE AND ADMINISTRATION

Apply a thin layer of ULTRAVATE lotion to the affected skin twice daily for up to two weeks. Rub in gently.

Discontinue therapy when control is achieved. If no improvement is seen within two weeks, reassessment of diagnosis may be necessary.

Treatment beyond two weeks is not recommended and the total dosage should not exceed 50 grams (50 mL) per week because of the potential for the drug to suppress the hypothalamic-pituitary-adrenal (HPA) axis [*see Warnings and Precautions 5.1*]. Do not use with occlusive dressings unless directed by a physician.

ULTRAVATE lotion is for external use only.

Avoid use on the face, scalp, groin, or axillae.

ULTRAVATE lotion is not for ophthalmic, oral, or intravaginal use.

3. DOSAGE FORMS AND STRENGTHS

ULTRAVATE (halobetasol propionate) lotion, 0.05% is a white to off-white lotion. Each gram of ULTRAVATE lotion contains 0.5 mg of halobetasol propionate.

4. CONTRAINDICATIONS

None.

5. WARNINGS AND PRECAUTIONS

5.1 Effects on Endocrine System

ULTRAVATE lotion is a topical corticosteroid that has been shown to suppress the hypothalamic-pituitary-adrenal (HPA) axis.

Systemic effects of topical corticosteroids may include reversible HPA axis suppression, with the potential for glucocorticosteroid insufficiency. This may occur during treatment or upon withdrawal of treatment of the topical corticosteroid.

The potential for hypothalamic-pituitary adrenal (HPA) suppression with ULTRAVATE lotion was evaluated in a study of 20 adult subjects with moderate to severe plaque psoriasis involving ≥20% of their body surface area. ULTRAVATE lotion produced HPA axis suppression when used twice daily for two weeks in 5 out of 20 (25%) adult patients with plaque psoriasis. Recovery of HPA axis function was generally prompt with the discontinuation of treatment [*see Clinical Pharmacology (12.2)*].

Because of the potential for systemic absorption, use of topical corticosteroids, including ULTRAVATE lotion, may require that patients be evaluated periodically for evidence of HPA axis suppression. Factors that predispose a patient using a topical corticosteroid to HPA axis suppression include the use of more potent corticosteroids, use over large surface areas, prolonged use, occlusive use, use on an altered skin barrier, concomitant use of multiple corticosteroid-containing products, liver failure, and young age. An ACTH stimulation test may be helpful in evaluating patients for HPA axis suppression.

If HPA axis suppression is documented, attempt to gradually withdraw the drug, reduce the frequency of application, or substitute a less potent steroid. Manifestations of adrenal insufficiency may require supplemental systemic corticosteroids. Recovery of HPA axis function is generally prompt and complete upon discontinuation of topical corticosteroids.

Systemic effects of topical corticosteroids may also include Cushing's syndrome, hyperglycemia, and glucosuria. Use of more than one corticosteroid-containing product at the same time may increase the total systemic exposure to topical corticosteroids.

Pediatric patients may be more susceptible than adults to systemic toxicity from the use of topical corticosteroids due to their larger surface-to-body mass ratios [*see Use in Specific Populations (8.4)*].

5.2 Local Adverse Reactions

Local adverse reactions from topical corticosteroids may include atrophy, striae, telangiectasias, burning, itching, irritation, dryness, folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, and miliaria. These may be more likely to occur with occlusive use, prolonged use, or use of higher potency corticosteroids, including ULTRAVATE lotion. Some local adverse reactions may be irreversible.

5.3 Concomitant Skin Infections

Use an appropriate antimicrobial agent if a skin infection is present or develops. If a favorable response does not occur promptly, discontinue use of ULTRAVATE lotion until the infection has been adequately treated.

5.4 Allergic Contact Dermatitis

Allergic contact dermatitis with corticosteroids is usually diagnosed by observing failure to heal rather than noting a clinical exacerbation. Consider confirmation of a clinical diagnosis of allergic contact dermatitis by appropriate patch testing. Discontinue ULTRAVATE lotion if allergic contact dermatitis is established.

6. ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

During randomized, controlled, blinded clinical trials 277 adults with plaque psoriasis were treated with ULTRAVATE lotion twice daily for up to two weeks (up to approximately 50 grams/week).

Table 1 presents adverse reactions that occurred in at least 1% of subjects treated with ULTRAVATE lotion twice daily for up to two weeks, and more frequently than in vehicle-treated subjects.

Table 1. Adverse Reactions Occurring in ≥ 1% of Subjects Treated with ULTRAVATE Lotion for up to Two Weeks

	ULTRAVATE Lotion (N=277)	Vehicle Lotion (N=259)
Adverse Reaction	%	%
Telangiectasia	1%	0%
Application site atrophy	1%	<1%
Headache	1%	<1%

Less common adverse reactions (incidence less than 1% but greater than 0.1%) that occurred in subjects treated with ULTRAVATE lotion included application site discoloration, herpes zoster, influenza, nasopharyngitis, otitis media acute, throat infection, wound, and increased blood pressure.

8. USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no data on topical halobetasol propionate use in pregnant women to inform any drug-associated risks for birth defects or miscarriage. In animal reproduction studies, halobetasol propionate administered systemically during organogenesis to pregnant rats at 13 and 33 times the human topical dose and to pregnant rabbits at 3 times the human topical dose resulted in teratogenic and embryotoxic effects [*see Data*]. The clinical relevance of the animal findings is not clear.

The background risk of major birth defects and miscarriage for the indicated population are unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Data

Animal Data

Halobetasol propionate has been shown to be teratogenic in rats and rabbits when given systemically during organogenesis at doses of 0.04 to 0.1 mg/kg/day in rats and 0.01 mg/kg/day in rabbits. These doses are approximately 13, 33, and 3 times, respectively, the human topical dose of halobetasol propionate, 0.05%. Halobetasol propionate was embryotoxic in rabbits but not in rats.

Cleft palate was observed in both rats and rabbits. Omphalocele was seen in rats, but not in rabbits.

8.2 Lactation

Risk Summary

There are no data on the presence of halobetasol propionate or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production after topical application to women who are breastfeeding.

Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ULTRAVATE lotion and any potential adverse effects on the breastfed infant from ULTRAVATE lotion or from the underlying maternal condition.

Clinical Considerations

Advise breastfeeding women not to apply ULTRAVATE lotion directly to the nipple and areola to avoid direct infant exposure.

8.4 Pediatric Use

Safety and effectiveness of ULTRAVATE lotion in patients younger than 18 years of age have not been established.

Because of higher skin surface area to body mass ratios, pediatric patients are at a greater risk than adults of HPA axis suppression and Cushing's syndrome when they are treated with topical corticosteroids. They are therefore also at greater risk of adrenal insufficiency during or after withdrawal of treatment. Adverse reactions including striae have been reported with use of topical corticosteroids in infants and children [*see Warnings and Precautions (5.1)*].

HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and an absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema [*see Warnings and Precautions (5.1)*].

8.5 Geriatric Use

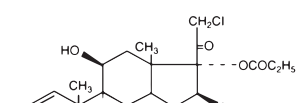
Clinical studies with ULTRAVATE lotion included 89 subjects aged 65 years and over. No overall differences in safety or effectiveness were observed between these patients and those younger than 65 years. Clinical studies of ULTRAVATE lotion did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

10. OVERDOSAGE

Topically applied ULTRAVATE lotion can be absorbed in sufficient amounts to produce systemic effects [*see Warnings and Precautions (5.1)*].

11. DESCRIPTION

ULTRAVATE (halobetasol propionate) lotion, 0.05% for topical use contains a corticosteroid, halobetasol propionate. The chemical name of halobetasol propionate is 21-chloro-6α, 9-difluoro-11β, 17-dihydroxy-16β-methylpregna-1, 4-diene-3-20-dione, 17-propionate. Halobetasol propionate is a white to off-white crystalline powder with a molecular weight of 484.96 and a molecular formula of $C_{25}H_{31}ClF_2O_5$. It is practically insoluble in water and freely soluble in dichloromethane and in acetone. It has the following structural formula:



Each gram of ULTRAVATE lotion contains 0.5 mg of halobetasol propionate in a white to off-white lotion base consisting of diisopropyl adipate, octyldodecanol, ceteth-20, poloxamer 407, cetyl alcohol, stearyl alcohol, propylparaben, butylparaben, propylene glycol, glycerin, carbomer homopolymer, sodium hydroxide, and water.

12. CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Corticosteroids play a role in cellular signaling, immune function, inflammation, and protein regulation; however, the precise mechanism of action in plaque psoriasis is unknown.

12.2 Pharmacodynamics

A vasoconstrictor assay in healthy subjects with ULTRAVATE lotion indicated that the formulation is in the super-high range of potency as compared to other topical corticosteroids; however, similar blanching scores do not necessarily imply therapeutic equivalence.

The potential for hypothalamic-pituitary adrenal (HPA) suppression was evaluated in a study of 20 adult subjects with moderate to severe plaque psoriasis. A mean dose of 3.5 grams ULTRAVATE lotion was applied twice daily for two weeks and produced HPA axis suppression in 5 of 20 (25%) patients. In this study, the criteria for HPA-axis suppression was a serum cortisol level of less than or equal to 18 micrograms per deciliter 30 minutes after stimulation with cosyntropin (adrenocorticotropic hormone). These effects were reversible as recovery of HPA axis function was generally prompt with the discontinuation of treatment [*see Warnings and Precautions (5.1)*].

12.3 Pharmacokinetics

The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings. Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin may increase percutaneous absorption.

In a Phase 2 HPA clinical study [*see Clinical Pharmacology (12.2)*], pharmacokinetics was evaluated in a subgroup of 12 adult subjects. On Day 8, blood was taken just prior to and at 1, 2, 4, 6, 8, and 12 hours following the last application. Plasma concentration of halobetasol propionate was measureable in all subjects. Based on the geometric mean plasma concentrations at 12 hour post-application across time, steady-state was achieved by Day 8. The mean (±standard deviation) C_{max} concentrations for ULTRAVATE lotion on Day 8 was 201.1 ± 157.5 pg/mL, with the corresponding median T_{max} value of 3 hours (range 0 – 6 hours); mean area under the halobetasol propionate concentration versus time curve over the dosing interval (AUC_T) was 1632 ± 1147 pg•h/mL.

13. NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been performed to evaluate the carcinogenic potential of halobetasol propionate.

In a 90-day repeat-dose toxicity study in rats, topical administration of halobetasol propionate lotion at dose concentrations from 0.05% to 0.1% or from 0.25 to 0.5 mg/kg/day of halobetasol propionate resulted in a toxicity profile consistent with long-term exposure to corticosteroids including adrenal atrophy, histopathological changes in several organ systems indicative of severe immune suppression, and opportunistic fungal and bacterial infections. A no observable adverse effect level (NOAEL) could not be determined in this study. Although the clinical relevance of the findings in animals to humans is not clear, sustained glucocorticoid-related immune suppression may increase the risk of infection and possibly the risk of carcinogenesis.

Halobetasol propionate was not found to be genotoxic in the Ames/Salmonella assay, in the Chinese hamster CHO/HGPRT assay, in the mouse micronucleus test, in the sister chromatid exchange test in somatic cells of the Chinese hamster, or in the chromosome aberration test in somatic cells of Chinese hamsters. Positive mutagenicity effects were observed in two genotoxicity assays: Chinese hamster nuclear anomaly test and mouse lymphoma gene mutation assay in vitro.

Studies in the rat following oral administration at dose levels up to 50 µg/kg/day indicated no impairment of fertility or general reproductive performance.

14. CLINICAL STUDIES

ULTRAVATE lotion was evaluated for the treatment of moderate to severe plaque psoriasis in two multicenter, randomized, double-blind, vehicle-controlled studies.

These studies were conducted in 443 subjects 18 years of age and older with plaque psoriasis involving between 2% and 12% body surface area. Baseline disease severity was determined using a static, five-level global evaluation scale, on which a subject scored either moderate or severe. Overall, 57% of subjects were male and 86% were Caucasian.

Subjects applied ULTRAVATE lotion or vehicle to all affected areas twice daily for up to 14 consecutive days.

The primary measure of efficacy was Overall Treatment Success, defined as the proportion of subjects who were cleared or almost cleared with at least a two grade improvement from baseline at Week 2 (end of treatment). Table 2 presents these results.

Table 2. Overall Treatment Success in Subjects with Plaque Psoriasis at Week 2

	Study 1		Study 2	
	ULTRAVATE Lotion N=110	Vehicle Lotion N=111	ULTRAVATE Lotion N=110	Vehicle Lotion N=112
Overall Treatment Success*	49 (44.5%)	7 (6.3%)	49 (44.5%)	8 (7.1%)

* Subjects whose condition was cleared or almost cleared of all signs of psoriasis and with at least a two grade improvement from baseline.

The secondary measures of efficacy were Treatment Success for individual signs of psoriasis (scaling, erythema, and plaque elevation) at the end of treatment (see Table 3).

Table 3. Individual Signs Treatment Success in Subjects with Plaque Psoriasis at Week 2

	Study 1		Study 2	
Treatment Success*	ULTRAVATE Lotion N=110	Vehicle Lotion N=111	ULTRAVATE Lotion N=110	Vehicle Lotion N=112
Scaling	61 (55.5%)	12 (10.8%)	65 (59.1%)	11 (9.8%)
Erythema	40 (36.4%)	8 (7.2%)	48 (43.6%)	12 (10.7%)
Plaque Elevation	50 (45.5%)	9 (8.1%)	48 (43.6%)	9 (8.0%)

* Subjects who were cleared or almost cleared of the designated clinical sign with at least a two grade improvement from baseline.

16. HOW SUPPLIED/STORAGE AND HANDLING

ULTRAVATE lotion, 0.05 % is white to off-white lotion. It is supplied in an oval tapered white high-density polyethylene bottle with a white polypropylene disc cap. Each bottle contains 60 mL (59g) of ULTRAVATE lotion.

NDC 10631-122-04 60 mL (59g) bottle
NDC 10631-122-51 120 mL (2-60 mL/59g bottles)

Store at 25°C (77°F); excursions permitted to 15ºC and 30ºC (59ºF to 86ºF) [see USP Controlled Room Temperature]. Do not freeze.

17. PATIENT COUNSELING INFORMATION

This information is intended to aid in the safe and effective use of this medication. It is not a disclosure of all administration instructions or all possible adverse or unintended effects.

Advise patients using ULTRAVATE lotion of the following information and instructions:

Important Administration Instructions

Instruct patients to discontinue ULTRAVATE lotion when psoriasis is controlled. ULTRAVATE lotion should not be used for longer than 2 weeks. Advise patients to contact the physician if no improvement is seen within 2 weeks. Inform patients that total dosage should not exceed 50 grams per week [*see Dosage and Administration (2)*].

Instruct patients to avoid bandaging, wrapping or otherwise occluding the treatment area(s), unless directed by physician. Advise patients to avoid use on the face, scalp, groin, or axillae [*see Dosage and Administration (2)*].

Inform patients that ULTRAVATE lotion is for external use only. Advise patients that ULTRAVATE lotion is not for ophthalmic, oral, or intravaginal use [*see Dosage and Administration (2)*].

Breastfeeding women should not apply ULTRAVATE lotion directly to the nipple and areola to avoid directly exposing the infant [*see Lactation (8.2)*].

Effects on Endocrine System

ULTRAVATE lotion may cause HPA axis suppression. Advise patients that use of topical corticosteroids, including ULTRAVATE lotion, may require periodic evaluation for HPA axis suppression. Topical corticosteroids may have other endocrine effects. Concomitant use of multiple corticosteroid-containing products may increase the total systemic exposure to topical corticosteroids [*see Warnings and Precautions (5.1)*].

Local Adverse Reactions

Inform patients that topical corticosteroids may cause local adverse reactions, some of which may be irreversible. These reactions may be more likely to occur with occlusive use, prolonged use or use of higher potency corticosteroids, including ULTRAVATE lotion [*see Warnings and Precautions (5.2)*].

Rx Only

ULTRAVATE is a registered trademark of Sun Pharmaceutical Industries, Inc.

Manufactured by: Ferndale Laboratories, Inc., Ferndale, MI 48220
Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512

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