HALOG® SOLUTION

(Halcinonide Topical Solution, USP) 0.1%

NOW AVAILABLE

for busy bodies with corticosteroid-responsive dermatoses (CRD) such as:

- **Scalp psoriasis**
- **Seborrheic dermatitis**

- **The only alcohol-free class 2 corticosteroid solution to help minimize burning and stinging**[1-4]
- **Suitable for scalp and hair-bearing areas**[5]
- **Relieves itch and inflammation**[1]
- **Nonirritating formulation**[1,4,6,7]

Are your scalp psoriasis patients itching for a solution?

Life doesn't come with a pause button, and **burning, stinging, and itching can be disruptive** to busy modern-day lifestyles.[8-10]

Busy bodies need a treatment option that **relieves itch without causing irritation or burning and stinging** upon application.

Help your patients keep up with the demands of their day.

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.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

PRECAUTIONS

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.

Please see additional Important Safety Information throughout and the accompanying Full Prescribing Information for complete prescribing details.

NONIRRITATING ALCOHOL-FREE FORMULATION TO HELP MINIMIZE BURNING AND STINGING[1,4,6,7]

NOW AVAILABLE

HALOG® SOLUTION

(Halcinonide Topical Solution, USP) 0.1%

Free of common irritating or allergenic ingredients[1,4,7]:

- No alcohol
- No propylene glycol
- No sulfates
- No parabens
- No fragrances

Cosmetically desirable for the scalp or hair-bearing areas[6]:

- Sodium lauryl sulfate-free to avoid damaging hair[1,11]
- Colorless and undetectable after application[6]
- Only 4 excipients[1]

IMPORTANT SAFETY INFORMATION

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. Application 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.

Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity. 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.

Please see additional Important Safety Information throughout and the accompanying Full Prescribing Information for complete prescribing details.

PROVEN CLASS 2 CORTICOSTEROID EFFICACY IN SCALP PSORIASIS[3,6]

In a 2-week efficacy study, HALOG® Solution demonstrated **superior efficacy** compared to a placebo solution and was well tolerated by patients.[6]

NOW AVAILABLE

HALOG® SOLUTION

(Halcinonide Topical Solution, USP) 0.1%

Comparative clinical response (%)[6]

Study (ML 1978): Patients with scalp psoriasis 2-week results (N=27) *P*<0.001

HALOG® Solution 81%

Placebo Solution 15%

4% of patients—equal

Evaluation of clinical response[6]

59%

Overall therapeutic response was rated as excellent in 59% of patients using HALOG® Solution compared with 4% of patients using the placebo solution (*P*<0.001).

Safety profile[6]

0%

No adverse reactions related to HALOG® Solution occurred in this study.

A newly-available solution to help minimize burning and stinging[1,4]

With proven efficacy in a nonirritating alcohol-free formulation, HALOG® Solution keeps up with the demands of modern-day lifestyles.[1,4,6,7]

IMPORTANT SAFETY INFORMATION

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.

Use in Specific Populations

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.

Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Caution should be exercised when topical corticosteroids are administered to a nursing woman.

Please see additional Important Safety Information throughout and the accompanying Full Prescribing Information for complete prescribing details.

THE ONLY ALCOHOL-FREE CLASS 2 CORTICOSTEROID SOLUTION for busy bodies with CRD such as[1-3]:

- Scalp psoriasis
- Seborrheic dermatitis

AN ECONOMICAL **120-mL** SQUEEZE BOTTLE*

Tapered tip for targeted application on hair-bearing areas.

*Compared to 60-mL for a leading generic class 2 corticosteroid solution.[2]

NOW AVAILABLE

HALOG® SOLUTION

(Halcinonide Topical Solution, USP) 0.1%

- **Alcohol-free to help minimize burning and stinging**[1,4]
- **Cosmetically desirable for the scalp**[6]
- **Proven efficacy in scalp psoriasis in as little as 2 weeks**[6]
- **Nonirritating formulation free of allergenic ingredients**[1,4,6,7]

Dosing: Apply to the affected area 2 to 3 times daily.[1]

A proven class 2 treatment option without certain prescribing restrictions[1,3,12]

No restrictions based on[1]:

- **Patient age**
- **Weekly dosage limits**
- **Body surface area**
- **Application to specific parts of the body**

Eligible commercially insured patients pay **as little as $0** per product per prescription with the **Co-Pay Card Savings Program***

No generic equivalent! Reinforce your decision to prescribe HALOG® Solution by writing DAW-1 every time.

*Prescriptions that may be reimbursed under federal or state healthcare programs (including Medicaid and Medicare) are not eligible under this program. Additional restrictions apply.

IMPORTANT SAFETY INFORMATION

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.

Please see additional Important Safety Information throughout and the accompanying Full Prescribing Information for complete prescribing details.

If you experience any Adverse Events you are encouraged to report them to the Drug Safety Department at 1-800-406-7984 or email Drug.Safety@ranbaxy.com. You can also report to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

References: 1. HALOG® Solution [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; 2019. **2.** Sun Pharmaceutical Industries, Inc. Data on File. 2019. **3.** Ference JD, Last AR. *Am Fam Physician.* 2009;79(2):135–140. **4.** Braun-Falco O, Plewig G, Wolff HH, Burgdorf WHC. *Dermatology.* 2nd ed. NY: Springer-Verlag Berlin Heidelberg; 2000. **5.** Feldman SR, Housman TS. *Am J Clin Dermatol.* 2003;4(4):221–224. **6.** Lepaw MI. *Cutis.* 1978;21(4):571-573. **7.** Scheman A. *Dermatol Clin.* 2000;18(4):685-698. **8.** Housman TS, Mellen BG, Rapp SR, Fleischer AB Jr, Feldman SR. *Cutis.* 2002;70(6):327–332. **9.** Blakely K, Gooderham M. *Psoriasis (Auckl).* 2016;6:33–40. **10.** Hill D, Farhangian ME, Feldman SR. *Dermatol Online J.* 2016;22(5):16. **11.** Cline A, Uwakwe LN, McMichael AJ. *Cutis.* 2018;101(1):22–26. **12.** ULTRAVATE® Lotion [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; 2017.

SUN DERMATOLOGY

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

For Topical Use Only. Not For Ophthalmic Use.

Rx Only

PPK-8860-0
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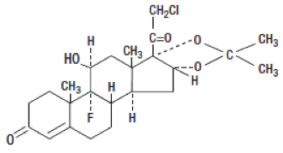
DESCRIPTION
The topical corticosteroids constitute a class of primarily synthetic steroids used as anti-inflammatory and antipruritic agents. The steroids in this class include halcinonide. Halcinonide is designated chemically as 21-Chloro-9-fluoro-11β,16α, 17-trihydroxypregn-4-ene-3,20-dione cyclic 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.

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SUN PHARMA

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