HALOG® SOLUTION (Halcinonide Topical Solution, USP) 0.1 %
For Topical Use Only. Not For Ophthalmic Use.
Rx Only

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-OH-9-fluoro-11b,16a, 17-trihydroxyprog-4-ene-3,20-dione cyclic 16,17-acetal with acetone. Structural formula:

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 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 dermatologic 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.

Teratogenic Effects
Corticosteroids are generally teratogenic in laboratory animals when administered during organogenesis. The results of animal reproduction studies are not always predictive of human response. Studies in rats and rabbits indicate that topical corticosteroids may reduce the number of offspring delivered and increase fetal resorption. When administered during organogenesis, topical corticosteroids may reduce fetal weight, although it is not known whether this represents true impairment of fetal growth or if reduced weight is merely a reflection of decreased fetal mortality due to topical corticosteroids.

The results of studies in animals indicate that topical corticosteroids can adversely affect the child's growth rate, behavior, and other physiologic functions. Studies have not been conducted to determine whether corticosteroids administered topically in amounts used in dermatology will produce these adverse effects in man. Growth retardation has been observed in infants treated with corticosteroids for prolonged periods. Therefore, topically applied corticosteroids should not be used on children if the alternative is not equally effective.

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 persons. In general, age is not a contraindication to the use of topical corticosteroids. However, aging of the skin may increase the frequency of adverse reactions to topical corticosteroids, and therefore, geriatric patients should receive topical corticosteroids with caution.

Pregnancy
It is not known whether topical corticosteroids can cause fetal harm when administered topically. However, systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression. Therefore, topically applied corticosteroids should not be used in pregnant women if the alternative is not equally effective.

Inhalation of topical corticosteroids has resulted in decreased growth rate in laboratory animals. Corticosteroids administered topically in amounts used in dermatology have not been shown to produce this effect in humans. Therefore, topically applied corticosteroids should not be used in children if the alternative is not equally effective.

In the presence of dermatologic 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.

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.
4-ene-3,20-dione cyclic 16,17-acetal with acetone. Structural formula: β

DESCRIPTION

Patients using topical corticosteroids should receive the following information and:

Information for the Patient

This preparation is not for ophthalmic use.

If irritation develops, topical corticosteroids should be discontinued and appropriate

Children may absorb proportionally larger amounts of topical corticosteroids and thus

material or adhesive and a substitute material may be necessary.

withdrawal may occur, requiring supplemental systemic corticosteroids.

Surface area or under an occlusive dressing should be evaluated periodically for evidence

Therefore, patients receiving a large dose of any potent topical steroid applied to a large

potent steroids, use over large surface areas, prolonged use, and the addition of

Conditions which augment systemic absorption include the application of the more

Systemic absorption of topical corticosteroids has produced reversible hypothalamic-

General

HALOG SOLUTION (Halcinonide Topical Solution, USP) 0.1% is indicated for the relief of

metabolites are also excreted into the bile.

bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in

(see DOSAGE AND ADMINISTRATION).

treatment of resistant dermatoses

HALOG SOLUTION (Halcinonide Topical Solution, USP) 0.1% contains 1 mg

hydroxytoluene as an antioxidant.

Each mL of 0.1% HALOG SOLUTION (Halcinonide Topical Solution, USP) contains 1 mg

5. Parents of pediatric patients should be advised not to use tight-fitting diapers or

3. The treated skin area should not be bandaged or otherwise covered or wrapped as to

be occlusive unless directed by the physician.

5. As long as the preparations are handled appropriately and the physician judges

inappropriate, patients should be advised not to use the medication on the eyes or

over large surface areas and for prolonged periods of time.

Topically applied corticosteroids can be absorbed in sufficient amounts to produce

skin atrophy, striae, and miliaria.

Allergic contact dermatitis, maceration of the skin, secondary infection,

folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis,

Topically applied corticosteroids can be absorbed in sufficient amounts to produce

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,

telangiectasia, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis,

allergic contact dermatitis, maceration of the skin, secondary infection; skin atrophy, striae, and milia.

Topically applied corticosteroids can be absorbed in sufficient amounts to produce

systemic effects (see PRECAUTIONS: General).

DOSE 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 10631-095-00), 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

Not for use in pediatrics: PPK-8660-0

Revised July 2019
HALOG® OINTMENT
(Halcinonide Ointment, USP) 0.1%
FOR TOPICAL USE ONLY.
NOT FOR OPHTHALMIC, ORAL, OR INTRAVAGINAL USE.

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-11\(\beta\),16\(\alpha\)-17-trihydroxyestrone-3,20-dione cyclic 16,17-acetal with acetone. Graphic formula:

![Graphic formula](image)

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 disterate with butylated hydroxytoluene as an antioxidant.

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

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 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).

Patients receiving topical corticosteroids should be evaluated periodically for evidence of HPA axis suppression and of potential adverse effects. Patience should not be lost if response is slow or unobtainable.

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.

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

INSERT SIZE: 8.00” X 5.75” (203 X 146 mm)
TRACKING: A27/08/2018
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 progestins 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 milia.

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

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 10631-096-15 Tube containing 15 g
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 (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

141012 Revised May 2018
The topical corticosteroids constitute a class of primarily synthetic steroids used as anti-inflammatory and anti-pruritic agents. The steroids in this class include halcinonide. Halcinonide, USP is designated chemically as 21-Chloro-9-fluoro-11-
\[\text{C}_{24}\text{H}_{32}\text{ClFO}_{5}\] 16,17-acetal with acetone. Graphic formula:

Each gram of 0.1% HALOG (Halcinonide Cream, USP) contains 1 mg halcinonide, USP in a specially formulated cream base consisting of alkyl alcohol, dimethicone, propylene glycol, petrolatum, sorbitan esters, propylene glycol, purified water, and titanium dioxide.

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

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

Corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. The increased 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 can be found in plasma in various 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.

DESCRIPTION
HALOG® (Halcinonide Cream, USP) 0.1% is smooth, soft homogeneous white to off-white cream, essentially free of foreign matter and is supplied in 15-gram tubes.

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

DOSAGE AND ADMINISTRATION
Topically applied corticosteroid can be absorbed in sufficient amounts to produce systemic effects (see WARNINGS: General).

The following are directions for the use of this drug:

1. The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by the physician.

2. The treated skin area should be washed and dried before application. The cream should be applied, without occlusion, during the day. Reapplication is essential at each dressing change.

3. The treated skin area should be washed and dried before application and seal the edges. If needed, additional moisture may be provided by covering the lesion with a dampened clean cotton cloth before the non-occlusive dressing is placed on the lesion. A barrier cream or lotion without corticosteroids also may be used under the occlusive dressing to prevent contact dermatitis from the rubber or plastic in the occlusive dressing.

4. Occlusive dressings are frequently used to increase the rate of penetration of topical corticosteroids into the skin. The use of occlusive dressings may be a valuable therapeutic adjunct for treatment of resistant dermatoses (see DOSAGE AND ADMINISTRATION).

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

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

Early childhood adrenal suppression has been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of adrenal insufficiency include losing weight, listlessness, and abdominal pain.

Corticosteroids are generally considered safe in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application to laboratory animals. There are no adequate and well-controlled studies in pregnant women onteratogenic 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 large areas, or for prolonged periods of time.

ADVERSE REACTIONS
The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings:

Allergic contact dermatitis reactions may be noted in an area approximately decreasing order of systemic action: burning, itching, stinging, redness, tenderness, pruritus, adrenocortical insufficiency, skin atrophy, striae, and telangiectasis.

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

WARNINGS: General
Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifested by decreased plasma cortisol levels and suppression of adrenocorticotrophic hormone (ACTH) secretion.

If all signs and symptoms of HPA axis suppression are present, it is necessary to determine the cause. This may require the patient to be temporarily removed from the treatment regimen.

If HPA axis suppression is noted, taper and stop the drug slowly. In the absence of HPA axis suppression or other contraindications, treatment of acute adrenal insufficiency (e.g., 12-hour occlusion) may be accomplished with a 40 mg oral dose of hydrocortisone the day prior to the scheduled dressing change. When the occlusive dressing has been in place from 12 to 14 hours, a single dose of 20 mg of hydrocortisone may be employed. In the absence of HPA axis suppression or other contraindications, treatment of acute adrenal insufficiency (e.g., 12-hour occlusion) may be accomplished with a 40 mg oral dose of hydrocortisone the day prior to the scheduled dressing change. When the occlusive dressing has been in place from 12 to 14 hours, a single dose of 20 mg of hydrocortisone may be employed.

Patients receiving systemic corticosteroids should taper slowly and the drug should be discontinued as rapidly as possible. Topical corticosteroids may also suppress adrenal function in patients with a recent history of severe stress, e.g., major surgery.

If the patient is on systemic corticosteroid therapy, systemic corticosteroids may be required. Consider tapering systemic corticosteroids prior to initiation of topical corticosteroids.

Children receiving prolonged therapy may be more susceptible to this suppression. If the child develops symptoms of adrenal insufficiency, increase the dose of systemic corticosteroid and repeat the dressing change at a longer interval. If symptoms persist, discontinue the use of topical corticosteroids and institute appropriate therapy.

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

Hormonal and Metabolism Effects
Corticosteroids are generally considered safe in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application to 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 large areas, or for prolonged periods of time.

ADVERSE REACTIONS
The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings:

ADVERSE REACTIONS
The following adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings:

Visual Mark: XM

RX only

Rx only

Cranbury, NJ 08512

Manufactured by:
DPT Laboratories Inc.
San Antonio, TX 78213

Distributed by:
SUN Pharmaceuticals Industries, Inc.
Cranbury, NJ 08512

Copyright 2018

Size : 5.75" x 8" (146 x 203 mm)
Color: Black
Track: A27/08/2018

Revised May 2018

I 2 of 5 value: 09-YYYY
C29H45O5\(\text{C}=\text{O}\)HCH3

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

**PHARMACOKINETICS**

The topical corticosteroids are absorbed from normal unbroken skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. The rate of penetration of steroid is determined by many factors, including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.

Corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corneocytes are lost to provide access in varying degrees. 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 severe skin reactions requiring hospitalization and prolonged corticosteroid therapy. Recovery of HPA axis function and thermal homeostasis are generally prompt and complete upon discontinuation of the drug. If recovery does not occur promptly, the corticosteroid should be discontinued and the patient should be observed for any signs of adrenal insufficiency.

**PRECAUTIONS**

- **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. In the presence of dermatological infections, the use of antifungal or antibacterial agents should be instituted. If a favorable response occurs, the topical corticosteroid may be used as an adjuvant after the infection has been brought under control with appropriate therapy.

- **Pregnancy**
  - The use of corticosteroids during pregnancy should be avoided if possible. There is no evidence to suggest that topical corticosteroids cause an increase in the rate of cleft lip and palate in human embryos. Nonetheless, systemic absorption of corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifested by decreased basal plasma cortisol levels, suppression of adrenocorticotropic hormone (ACTH) stimulation, and suppression of endogenous ACTH secretion. Therefore, if topical corticosteroids are used in pregnant women, they should be used sparingly. If topical corticosteroids are used during pregnancy, it should be done only if possible benefit to the mother justifies potential risk to the fetus. Drugs of this class should not be used extensively on large areas of the body, nor should the total amount of topical corticosteroids be used systematically with other potentially similar agents or systemic corticosteroids. Ophthalmic preparations of corticosteroids are not systemically absorbed and therefore are not expected to produce adrenal suppression or Cushing's syndrome in infants and children.

- **Lactation**
  - It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities of drug in the breast milk. Systemically administered corticosteroids are not transferred in quantities sufficient to produce clinical effects in nursing infants.

**ADVERSE REACTIONS**

- **Local**
  - The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, and induration.

- **Systemic**
  - Systemic adverse reactions may also occur with these preparations and can be more pronounced with the use of occlusive dressings. They include: alterations in carbohydrate metabolism,欣长, weight, and fat redistribution; increased skin fragility; premature osteoporosis; growth retardation in children; hyperglycemia in diabetics; and adrenal insufficiency.

**INTERACTIONS**

- Rare instances of exacerbation of dermatitis, systemic adrenal suppression, Cushing's syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids.

**DOSAGE AND ADMINISTRATION**

The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, and induration.

**DOSAGE**

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (see PRECAUTIONS: General). The use of occlusive dressings with the topical corticosteroids may result in higher and more rapid systemic absorption.

**DIRECTIONS FOR USE**

Follow your doctor's instructions for the use of this medication. If you have any questions about the use of this medication, please consult your doctor or pharmacist.

**Rx only**

**HALOG® (Halcinonide Cream, USP) 0.1%** is smooth, soft homogeneous white to off-white cream, essentially free of foreign matter and is supplied as 60 g in a plastic tube. DPT Laboratories Inc., Cranbury, NJ 08512, manufactured by: DPT Laboratories, Inc., San Antonio, TX 78223. Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512. Revised May 2013

**HALOG® (Halcinonide Cream, USP) 0.1%** is a white, semisolid homogenous cream for topical administration. It is supplied as 60 g in a plastic tube. This product contains alcohol, cellulose, cetyl alcohol, dimethicone 350, glyceryl monostearate, isopropyl palmitate, polysorbate 60, propylene glycol, purified water, and litunum oxide.

**INDICATIONS AND USAGE**

- **Topical**
  - For the management of dermatomic disorders. The active ingredient is also used as an adjuvant in the procedure of dermatorrafia.

**PRECAUTIONS**

- **Systemic**
  - Systemic absorption of corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifesting by decreased basal plasma cortisol levels, suppression of adrenocorticotropic hormone (ACTH) stimulation, and suppression of endogenous ACTH secretion. Therefore, if topical corticosteroids are used in pregnant women, they should be used sparingly. If topical corticosteroids are used during pregnancy, it should be done only if possible benefit to the mother justifies potential risk to the fetus. Drugs of this class should not be used extensively on large areas of the body, nor should the total amount of topical corticosteroids be used systematically with other potentially similar agents or systemic corticosteroids. Ophthalmic preparations of corticosteroids are not systemically absorbed and therefore are not expected to produce adrenal suppression or Cushing's syndrome in infants and children.

- **Pediatric**
  - 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. In the presence of dermatological infections, the use of antifungal or antibacterial agents should be instituted. If a favorable response occurs, the topical corticosteroid may be used as an adjuvant after the infection has been brought under control with appropriate therapy.

**PRECAUTIONS: General**

- The use of corticosteroids during pregnancy should be avoided if possible. There is no evidence to suggest that topical corticosteroids cause an increase in the rate of cleft lip and palate in human embryos. Nonetheless, systemic absorption of corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifested by decreased basal plasma cortisol levels, suppression of adrenocorticotropic hormone (ACTH) stimulation, and suppression of endogenous ACTH secretion. Therefore, if topical corticosteroids are used in pregnant women, they should be used sparingly. If topical corticosteroids are used during pregnancy, it should be done only if possible benefit to the mother justifies potential risk to the fetus. Drugs of this class should not be used extensively on large areas of the body, nor should the total amount of topical corticosteroids be used systematically with other potentially similar agents or systemic corticosteroids. Ophthalmic preparations of corticosteroids are not systemically absorbed and therefore are not expected to produce adrenal suppression or Cushing's syndrome in infants and children.

**EQUIVALENTS**

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