For the use of Dermatologists or a Hospital or a Laboratory only

HALONOVA

1. **Generic Name**

   Halobetasol Propionate Cream 0.05 % w/w

2. **Qualitative and quantitative Composition:**

   Halobetasol Propionate U.S.P. …0.05 % w/w

   Chlorocresol I.P. ……...0.1 % w/w

   In a cream base ……. q.s.

   The list of excipients used are Cetosteryl Alcohol, Cetomacrogol, Patroleum Jelly White, Heavy Liquid Paraffin.

3. **Dosage form and strength**

   Dosage form: Cream

   Strength: 0.05 % w/w

4. **Clinical particulars**

4.1. Therapeutic indication

Halobetasol propionate cream is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

4.2. Posology and method of administration

Posology

Apply a thin layer of Halobetasol Propionate Cream to the affected skin once or twice daily, as directed by your physician, and rub in gently and completely.

Halobetasol Propionate Cream is a super-high potency topical corticosteroid; therefore, treatment should be limited to two weeks, and amounts greater than 50 g/week should not be used. As with other corticosteroids, therapy should be discontinued when control is achieved. If no improvement is seen within 2 weeks, reassessment of diagnosis may be necessary.

Halobetasol Propionate Cream should not be used with occlusive dressings.

Method of administration

For topical use only.

4.3. Contraindications

Halobetasol Propionate Cream is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

4.4. Special warnings and precautions for use

General

Systemic absorption of topical corticosteroids can produce reversible hypothalamic pituitary adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycemia, and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment.

Patients applying a topical steroid to a large surface area or to areas under occlusion should be evaluated periodically for evidence of HPA axis suppression. This may be done by using the ACTH stimulation, A.M. plasma cortisol, and urinary free-cortisol tests. Patients receiving super potent corticosteroids should not be treated for more than 2 weeks at a time and only small areas should be treated at any one time due to the increased risk of HPA suppression.

Halobetasol Propionate Cream produced HPA axis suppression when used in divided doses at 7 grams per day for one week in patients with psoriasis. These effects were reversible upon discontinuation of treatment.

If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent corticosteroid. Recovery of HPA axis function is generally prompt upon discontinuation of topical corticosteroids. Infrequently, signs and symptoms of glucocorticosteroid insufficiency may occur requiring supplemental systemic corticosteroids. For information on systemic supplementation, see prescribing information for those products.

Pediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios.

If irritation develops, Halobetasol Propionate Cream should be discontinued, and appropriate therapy instituted. Allergic contact dermatitis with corticosteroids is usually diagnosed by observing failure to heal rather than noting a clinical exacerbation as with most topical products not containing corticosteroids. Such an observation should be corroborated with appropriate diagnostic patch testing.

If concomitant skin infections are present or develop, an appropriate antifungal or antibacterial agent should be used. If a favourable response does not occur promptly, use of Halobetasol Propionate Cream should be discontinued until the infection has been adequately controlled.

Halobetasol Propionate Cream should not be used in the treatment of rosacea or perioral dermatitis, and it should not be used on the face, groin, or in the axillae.

4.5. Drugs interactions

None known.

4.6. Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

Pregnancy

Teratogenic effects: Pregnancy Category C

Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application in laboratory animals.

Halobetasol propionate has been shown to be teratogenic in SPF rats and chinchilla-type rabbits when given systemically during gestation at doses of 0.04 to 0.1 mg/kg in rats and 0.01 mg/kg in rabbits. These doses are approximately 13, 33 and 3 times, respectively, the human topical dose of Halobetasol Propionate Cream. 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.

There are no adequate and well-controlled studies of the teratogenic potential of halobetasol propionate in pregnant women. Halobetasol Propionate Cream should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

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. Because many drugs are excreted in human milk, caution should be exercised when Halobetasol Propionate Cream is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of Halobetasol Propionate Cream in pediatric patients have not been established and use in pediatric patients under 12 is not recommended. Because of a higher ratio of skin surface area to body mass, 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 effects including striae have been reported with inappropriate use of topical corticosteroids in infants and children.

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.

Geriatric Use

Of approximately 400 patients treated with Halobetasol Propionate Cream in clinical studies, 25% were 61 years and over and 6% were 71 years and over. No overall differences in safety or effectiveness were observed between these patients and younger patients; and 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.

4.7. Effects on ability to drive and use machines

There are no data on the effect of this product on driving capacity and use of machines. An effect is however, unlikely.

4.8. Undesirable effects

In controlled clinical trials, the most frequent adverse events reported for Halobetasol Propionate Cream included stinging, burning or itching in 4.4% of the patients. Less frequently reported adverse reactions were dry skin, erythema, skin atrophy, leukoderma, vesicles and rash.

The following additional local adverse reactions are reported infrequently with topical corticosteroids, and they may occur more frequently with high potency corticosteroids, such as Halobetasol Propionate Cream. These reactions are listed in an approximate decreasing order of occurrence: folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, striae and miliaria.

Reporting of adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Report suspected adverse reactions via any point of contact available at www.torrentpharma.com.

4.9. Overdose

Topically applied Halobetasol Propionate Cream can be absorbed in sufficient amounts to produce systemic effects.

5. Pharmacological properties

5.1. Mechanism of Action

Like other topical corticosteroids, halobetasol propionate has anti-inflammatory, antipruritic and vasoconstrictive actions.

5.2. Pharmacodynamic properties

The mechanism of the anti-inflammatory activity of the topical corticosteroids, in general, is unclear. However, corticosteroids are thought to act by the induction of phospholipase A inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A2.

5.3. Pharmacokinetic properties

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle and the integrity of the epidermal barrier. Occlusive dressings with hydrocortisone for up to 24 hours have not been demonstrated to increase penetration; however, occlusion of hydrocortisone for 96 hours markedly enhances penetration. Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin may increase percutaneous absorption.

Human and animal studies indicate that less than 6% of the applied dose of halobetasol propionate enters the circulation within 96 hours following topical administration of Halobetasol Propionate Cream.

Studies performed with Halobetasol Propionate Cream indicate that it is in the super-high range of potency as compared with other topical corticosteroids.

6. Nonclinical properties

6.1. Animal Toxicology or Pharmacology

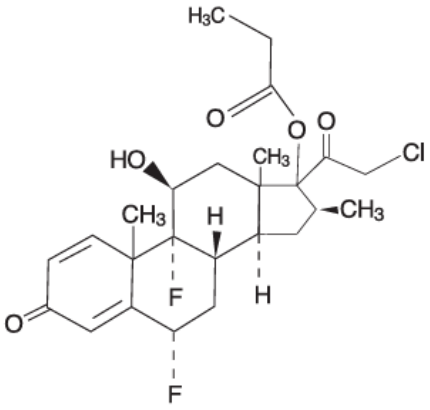
Long-term animal studies have not been performed to evaluate the carcinogenic potential of halobetasol propionate. Positive mutagenicity effects were observed in two genotoxicity assays. Halobetasol propionate was positive in a Chinese hamster micronucleus test, and in a mouse lymphoma gene mutation assay *in vitro*.

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

In other genotoxicity testing, halobetasol propionate was not found to be genotoxic in the Ames/Salmonella assay, in the sister chromatid exchange test in somatic cells of the Chinese hamster, in chromosome aberration studies of germinal and somatic cells of rodents, and in a mammalian spot test to determine point mutations.

7. Description

Halobetasol Propionate is [(6S,8S,9R,10S,11S,13S,14S,16S,17R)-17-(2-chloroacetyl)-6,9-difluoro-11-hydroxy-10,13,16-trimethyl-3-oxo-6,7,8,11,12,14,15,16-octahydrocyclopenta[a]phenanthren-17-yl] propanoate. The empirical formula is $C_{25}H_{31}ClF_2O_5$ and its molecular weight is 485.0 g/mol. The chemical structure of Halobetasol Propionate is:



Halonova

Halonova is white, smooth cream, free from lumps. The list of excipients used are Cetosteryl Alcohol, Cetomacrogol, Patroleum Jelly White, Heavy Liquid Paraffin.

8. Pharmaceutical particulars

8.1. Incompatibilities

Not applicable

8.2. Shelf-life

Do not use later than the date of expiry.

8.3. Packaging information

Halonova is available in tube of 15 gm.

8.4. Storage and handing instructions

Store at a temperature not exceeding 25^0 C.

Do not freeze, Protect from light.

Keep out of reach of children.

Keep the cap tightly closed after use.

For external use only.

9. Patient Counselling Information

Ask the patients to inform the treating physicians in case of any of the below:

- Have any allergies
- Have kidney or liver problems
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Have any serious illness
- Are taking any medicines (prescription, over-the-counter, vitamins, or herbal products)

10. Details of manufacturer

Helios Pharmaceuticals

(Div. of P.K.T.P. Pvt. Ltd.)

Village Malpur, P.O. Bhud, Tehsil Nalagarh,

Baddi, Dist. Solan, (H.P.) -173 205.

11. **Details of permission or licence number with date**

    Mfg. Lic. No. is MNB/05/280, issue on 01.04.2016

12. **Date of revision**

    MAR 2026

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

IN/HALONOVA Cream 0.05 % w/w/MAR-2026/02/PI