

PRODUCT INFORMATION

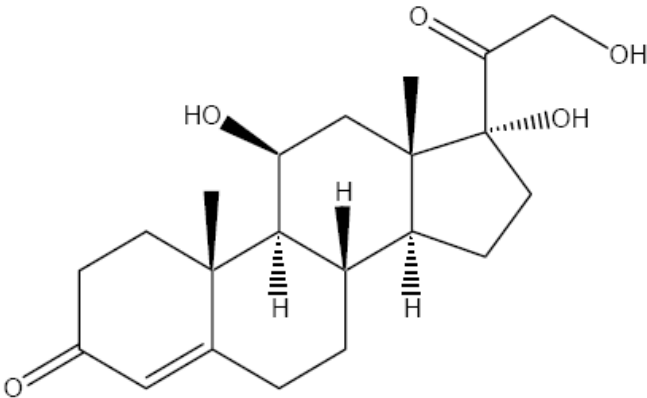
HYDROFORM[®] 1% CREAM

NAME OF THE MEDICINE

HYDROFORM cream contains hydrocortisone 1% w/w and clioquinol 1% w/w in a water-miscible cream base.

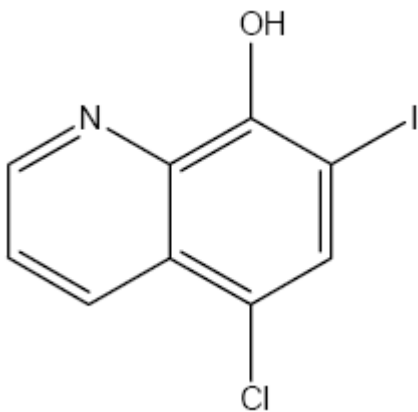
Hydrocortisone is 11 β , 17, 21-trihydroxypregn-4-ene-3,20-dione.

CAS Number: 50-23-7



Clioquinol is 5-chloro-7-iodo-8-quinolinol.

CAS Number: 130-26-7



DESCRIPTION

HYDROFORM cream contains hydrocortisone 1%, clioquinol 1% in a base containing: cetomacrogol 1000, chlorocresol, glycerol, cetostearyl alcohol, light liquid paraffin, soft white paraffin, propylene glycol, sodium hydroxide, lactic acid and purified water.

HYDROFORM is a topical compound for dermatological use, combining the antifungal and antibacterial actions of clioquinol and the anti-inflammatory and antipruritic effects of hydrocortisone to provide broad control of acute and chronic dermatoses.

PHARMACOLOGY

In vitro studies have demonstrated that HYDROFORM effectively inhibits the growth of various mycotic organisms such as Microsporons, Trichophytos and *Candida albicans* and Gram-positive cocci such as Staphylococci and Enterococci. The role of steroids in alleviating the inflammation and pruritus associated with many dermatoses has been well established.

Percutaneous absorption of both hydrocortisone and clioquinol has been demonstrated and is determined by many factors including use of occlusive dressings and the integrity of the epidermal barrier. Inflammation and/or other disease processes in the skin may increase percutaneous absorption. Percutaneous absorption of up to 40% of the dose of clioquinol has been reported following application under occlusive dressings.

INDICATIONS

HYDROFORM is indicated for use by adults in a wide variety of local inflammatory, pruritic and allergic disorders of the skin: Atopic dermatitis, contact dermatitis, seborrhoeic dermatitis and intertrigo with or without *Candida*.

CONTRAINDICATIONS

- Hypersensitivity to HYDROFORM Cream or any of its components (see Description).
- Hypersensitivity to iodine.
- Lesions of the eye.
- Tuberculosis of the skin and other primary bacterial or fungal infections of the skin.
- Viral skin lesions (including herpes simplex, vaccinia and varicella).
- Cutaneous infections caused by *Pseudomonas* species.
- Rosacea.
- Acne vulgaris.
- Pruritis without inflammation.

- Use in children. HYDROFORM Cream should not be used in children or infants because of the risk of irreversible optic atrophy and peripheral neuropathy.

PRECAUTIONS

The use over extensive skin areas may result in systemic absorption of both hydrocortisone and clioquinol - particularly with occlusive skin dressings. Therefore, use in large amounts or for long periods of time should be avoided.

Manifestations of hypercortisolism (Cushing's syndrome) and reversible hypothalamic-pituitary-adrenal (HPA) axis suppression can occur in some individuals as a result of increased systemic absorption of topical corticosteroids. If either of the above are observed, withdraw the treatment gradually by reducing the frequency of application, or by substituting a less potent corticosteroid. Abrupt withdrawal of treatment may result in glucocorticosteroid insufficiency (see ADVERSE REACTIONS).

Risk factors for increased corticosteroidal systemic effects are:

- Potency and formulation of topical corticosteroid
- Duration of exposure
- Application to a large surface area
- Use on occluded areas of skin e.g. on intertriginous areas or under occlusive dressings (nappies may act as an occlusive dressing)
- Increasing hydration of the stratum corneum
- Use on thin skin areas such as the face
- Use on broken skin or other conditions where the skin barrier may be impaired

Recovery of HPA-axis function is generally prompt and complete following discontinuation of the drug. In some patients, signs and symptoms of steroid withdrawal may occur, necessitating supplemental systemic corticosteroid therapy.

Patients receiving large doses of a topical corticosteroid, applied to extensive areas or under an occlusive dressing, should be evaluated periodically for evidence of HPA-axis suppression by using the urinary free cortisol test or the corticotropin stimulation test.

Therapy with topical corticosteroids should be discontinued gradually as rebound of pre-existing dermatoses can occur if stopped abruptly.

Contact Sensitisation

Extended or recurrent application of hydrocortisone with clioquinol may increase the risk of contact sensitisation. If local irritation, rash and sensitivity reactions occur the product should be discontinued.

Cross sensitivity with other hydroquinolone and quinoline derivatives, and occasionally to iodides, can occur.

Infection risk with occlusion

Bacterial infection is encouraged by the warm, moist conditions within skin folds or caused by occlusive dressings. When using occlusive dressings, the skin should be cleansed before a fresh dressing is applied.

Infection

Extension of the infection may occur due to the masking effect of the steroid. Any spread of infection requires withdrawal of topical corticosteroid therapy and administration of appropriate antimicrobial therapy.

Application to the face

Prolonged application to the face is undesirable as this area is more susceptible to atrophic changes.

Application to the eyelids

If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as cataracts and glaucoma might result from repeated exposure.

Chronic leg ulcers

Topical corticosteroids are sometimes used to treat the dermatitis around chronic leg ulcers. However, this use may be associated with a higher occurrence of local hypersensitivity reactions and an increased risk of local infection.

Diabetes Mellitus

Use cautiously in patients with diabetes mellitus. These patients may require adjustments in diet, insulin or hypoglycaemic agents.

Staining

This medicine may turn yellow in colour when exposed to air. It may cause yellow staining of skin, hair, nails and fabrics, including clothing and bed linen.

A light, permeable dressing may be used as a protective measure.

Dilution

Products which contain antimicrobial agents should not be diluted.

Use in pregnancy

Topical corticosteroids should be used during pregnancy only when the potential benefits justify the possible risks to the foetus. Use over extensive areas, in large amounts or for a prolonged period is not recommended. The minimum quantity should be used for the minimum duration.

The risk to the foetus born after exposure to clioquinol has not been determined.

Use in lactation

Because of possible percutaneous absorption of both hydrocortisone and clioquinol, and therefore secretion in breast milk, administration should only be considered if the expected benefit to the mother outweighs the risk to the infant.

If used during lactation, the cream should not be applied to the breasts to avoid accidental ingestion by the infant.

Paediatric use

Not to be used on infants and children under 12 years of age (see CONTRAINDICATIONS).

Elderly

The minimum quantity should be used for the shortest duration to achieve the desired clinical benefit.

Renal / Hepatic Impairment

The minimum quantity should be used for the shortest duration to achieve the desired clinical benefit.

Effects on Laboratory Tests

Clioquinol may be absorbed through the skin and interfere with thyroid function tests. If such tests are contemplated, wait at least one month between discontinuation of therapy and performance of these tests. The ferric chloride test for phenylketonuria (PKU) can yield a false positive result if clioquinol is present in the urine.

INTERACTIONS WITH OTHER MEDICINES

There are no generally recognised drug interactions attributable to topical hydrocortisone or clioquinol.

ADVERSE EFFECTS

There have been a few reports of rash and hypersensitivity. The following local adverse reactions have been reported with topical corticosteroids, especially under occlusive dressings: burning; itching; irritation; dryness; folliculitis; hypertrichosis; acneform eruptions; hypopigmentation; perioral dermatitis; allergic contact dermatitis; maceration of the skin; secondary infection; skin atrophy; striae; miliaria. Discontinue therapy if any untoward reaction occurs.

There is a known association between oculotoxic/ neurotoxic effects, e.g. optic neuritis, optic atrophy, subacute myelo-optic neuropathy (SMON), and oral clioquinol therapy (usually at high dosages for prolonged periods).

Post-marketing data

Adverse drug reactions (ADRs) are listed below by MedDRA system organ class and by frequency. Frequencies are defined as: very common ($\geq 1/10$), common ($\geq 1/100$ and $< 1/10$), uncommon ($\geq 1/1,000$ and $< 1/100$), rare ($\geq 1/10,000$ and $< 1/1,000$) and very rare ($< 1/10,000$), including isolated reports.

Endocrine Disorders

Very rare: Hypothalamic-pituitary adrenal (HPA) axis suppression: Increased weight gain/obesity, delayed weight gain/growth retardation in children, cushingoid features (e.g. moon face, central obesity), decreased endogenous cortisol levels, hyperglycaemia/glucosuria, hypertension, osteoporosis, cataract, glaucoma, steroid withdrawal syndrome

Skin and Subcutaneous Tissue Disorders

Very rare: Erythema, urticaria, skin pain, skin exfoliation, exacerbation of underlying symptoms, hair discolouration

DOSAGE AND ADMINISTRATION

HYDROFORM cream is for external use only.

A small amount of HYDROFORM cream should be applied to the affected area 3 or 4 times a day in a thin layer. Use of an occlusive dressing should normally be avoided.

Treatment should not be continued for more than seven days without medical supervision. If the condition worsens, or does not improve within seven days, treatment and diagnosis should be re-evaluated.

Failure to improve after seven days of treatment may indicate the need for a local systemic antibiotic, in place of HYDROFORM Cream, to control an associated infection. HYDROFORM Cream should not be used continuously long-term because of the risks of systemic absorption and overgrowth of non-susceptible organisms.

OVERDOSAGE

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects. If accidental ingestion of large quantities occurs, use non-specific means to eliminate the drug and reduce its absorption.

PRESENTATION AND STORAGE CONDITIONS

HYDROFORM cream is presented in tubes of 2 g, 30 g, 60 g or 100 g containing hydrocortisone 1% w/w and clioquinol 1% w/w.

Not all pack sizes may be distributed in Australia.

Store below 30°C.

POISONS SCHEDULE

Prescription Only Medicine.

NAME AND ADDRESS OF THE SPONSOR

GlaxoSmithKline Australia Pty Ltd
Level 4
436 Johnston Street
Abbotsford, Victoria 3067
AUSTRALIA

DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS (THE ARTG)

14 March 1995

Date of most recent amendment: 21 February 2014

HYDROFORM is a trade mark of Stiefel Laboratories, Inc.

Version 4.0

