NEW ZEALAND DATA SHEET

1. topiderm® Hydrocortisone acetate 1% Cream

Hydrocortisone acetate 1% w/w cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Hydrocortisone acetate 1% w/w
For the full list of excipients, see **Section 6.1 List of excipients**.

3. PHARMACEUTICAL FORM

Opaque off-white viscous topical cream.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

For the temporary relief of symptoms associated with acute and chronic corticosteroid responsive conditions, including minor skin irritations, itching and rashes due to eczema, dermatitis, (such as rashes due to cosmetics and jewellery), psoriasis, anogenital pruritus, and sunburn.

4.2. Dose and method of administration

Adults and children 2 years of age and older:
Apply to affected area not more than 3 – 4 times daily.

Children under 2 years of age:
Do not use, consult a doctor.

Reduce the number of applications as symptoms subside.

Rebound of pre-existing dermatoses can occur with abrupt discontinuation of topical corticosteroid preparations.

topiderm® Hydrocortisone acetate 1% Cream should not be used under bandages or dressings except on medical advice.

4.3. Contraindications

Hypersensitivity to hydrocortisone acetate or to any of the excipients listed in **Section 6.1 List of excipients**.

- Do not use on acne
- Hypersensitivity to any of the ingredients
- Do not use in the eye

Like all other topical corticosteroids, topiderm® Hydrocortisone acetate 1% Cream is contraindicated in skin infections and infestations such as chicken pox, herpes and other viral infections.

Hydrocortisone may mask signs of infection. If any infection is present, an appropriate anti-infective agent should be used first. topiderm® Hydrocortisone acetate 1% Cream may be used to reduce inflammation but if a favourable response does not occur promptly then use of the product should be discontinued until the infection has been adequately controlled.

If any skin irritation develops discontinue use and treat appropriately. If extensive areas are treated, or if occlusive dressings are used, the possibility also exists for increased systemic absorption and this could in turn lead to the depression of the hypothalamo-pituitary-adrenal axis. In all such patients it is essential to monitor adrenal function at regular intervals.

4.4. Special warnings and precautions for use

Long-term continuous topical therapy should be avoided where possible, particularly in children, as adrenal suppression can occur (even without occlusion). Use of the product near the eyes should be avoided.

As with other topical corticosteroids, when extensive areas are treated, sufficient systemic absorption may occur to produce the features of hypercorticalism. This effect is more likely to result if occlusive dressings are used or if treatment is prolonged. Rarely, local atrophy or striae may occur after prolonged treatment. This must be borne in mind when treating conditions such as severe eczema and seborrheic dermatitis. If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye as glaucoma may result.

Appropriate antimicrobial therapy should be used whenever treating inflammatory lesions that have become infected.

Topical corticosteroids should be used with caution in patients with primary skin infections. Any spread of the infection requires withdrawal of corticosteroid therapy and systemic administration of antimicrobial agents. Bacterial infection is encouraged by the warm, moist conditions associated by occlusive dressings, so the skin should be cleansed prior to a fresh dressing being applied.

Patients in whom there is a risk of increased systemic absorption should be regularly evaluated for evidence of hypothalmic-pituitary-adrenal (HPA) axis suppression by using urinary free cortisol (hydrocortisone) tests and monitoring morning plasma cortisol levels.

If there is evidence of suppression, attempts should be made to withdraw the drug or reduce the frequency of application. If hypersensitivity occurs, stop application and institute appropriate therapy. If irritation occurs, discontinue use. Systemic absorption of topical corticosteroids will be increased if extensive body surface areas are treated or if occlusion is used. Suitable precautions should be taken under these conditions or when long-term use is anticipated.

Withdrawal of corticosteroid therapy may exacerbate psoriasis. The frequency of application should be reduced before withdrawing the therapy.

Paediatric population

The risk of systemic absorption, and hence systemic toxicity, is greater in children due to a larger skin surface to body weight ratio than adults. The preparation is not recommended for use in children under 2 years of age except on the advice of a doctor.

4.5. Interaction with other medicines and other forms of interaction

There are currently no known drug interactions associated with the topical application of hydrocortisone.

4.6. Fertility, pregnancy and lactation

Pregnancy

Category A: Drugs which have been taken by a large number of pregnant women and women of child bearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the foetus having been observed.

Breast-feeding

It is not known whether sufficient absorption of topical corticosteroids takes place to be excreted in breast milk. The potential benefits should be weighed against possible hazards to the breastfeeding infant.

Fertility

No information available.

4.7. Effects on ability to drive and use machines

Presumed to be safe or unlikely to produce an effect on the ability to drive or use machinery.

4.8. Undesirable effects

After the application of topiderm® Hydrocortisone acetate 1% Cream a slight stinging sensation may occasionally be noticed. This transient symptom is most likely to disappear after several applications.

topiderm® Hydrocortisone acetate 1% Cream should not be used under bandages or dressings except on medical advice. Intolerance to the occlusive dressing (Miliary eruptions, folliculitis) may be expected to be observed, as with other corticosteroids. In such cases the use of an occlusive dressing should be discontinued. Use of the steroid may also need to be reduced or discontinued as local atrophy and striae of the skin may be observed.

In long-term treatment of extensive skin areas with occlusive dressings, one should bear in mind the possibility of inhibition of adrenal function. Therefore, adrenal function should be monitored under these circumstances.

The following adverse effects have been reported with topical steroids: burning, itching, irritation, skin atrophy, secondary infections, dryness, acneform eruptions and hypo-pigmentation. Treatment should be chiefly symptomatic and administration of the steroids should be discontinued.

General disorders and administration site conditions

Rebound effect – see **Section 4.2 Dose and method of administration**.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/

4.9. Overdose

Percutaneous absorption of corticosteroids may occur, especially under occlusive conditions. The following adverse effects have been reported with topical steroids: burning; itching; irritation; skin atrophy; secondary infection; dryness; acneform eruptions and hypo-pigmentation. Treatment should be chiefly symptomatic and administration of the steroid should be discontinued.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

topiderm® Hydrocortisone acetate 1% Cream contains hydrocortisone. Hydrocortisone has anti-inflammatory, anti-eczematous, anti-allergic and anti-pruritic properties.

Pharmacotherapeutic group: Dermatologicals Corticosteroid weak, ATC code: D07AA02.

Mechanism of action

When applied topically, hydrocortisone diffuses across cell membranes to form complexes with specific cytoplasmic receptors. These complexes enter the cell nucleus, bind to DNA, and stimulate transcription of messenger RNA and subsequent protein synthesis of enzymes responsible for anti-inflammatory effects, including inhibition of oedema, fibrin deposition, capillary dilation, and movements of phagocytes. Later stages of inflammation such as capillary production, collagen deposition, and keloid formation are also inhibited.

At a concentration of 1%, topically applied hydrocortisone has been found to bring about both subjective and objective improvements, usually within one week and often as soon as 24 to 48 hours after initiation of therapy. Systemic effects from prolonged external application of large amounts of hydrocortisone to wide areas of damaged skin have been minimal. Adrenal axis suppression has not been observed.

5.2. Pharmacokinetic properties

Absorption

Hydrocortisone is absorbed through the skin allowing penetration to the deeper layers. The extent of absorption is greater for inflamed skin and other skin conditions such as eczema and psoriasis. Absorption is also greater in areas such as the ear, scrotum, axillae, face and scalp. Absorption is aided

by occlusive dressings due to the resulting hydration of the skin. Once absorbed, the pharmacokinetics are similar to systemic steroids.

Distribution

Following topical application, hydrocortisone diffuses through the skin by both transfollicular and transepidermal routes. Absorption varies according to anatomic site of application and ranges from 1% (forearm skin) to 26 – 29% (mucous membranes). Factors influencing penetration include concentration, vehicle, anatomic site, age, condition of the skin, and occlusion. The plasma level of hydrocortisone falls to 50% of its initial concentration in 90 minutes; the biological half-life of hydrocortisone is 8 – 12 hours. Biotransformation takes place primarily in the skin, and for any amount absorbed systematically, in the liver. 0.2% - 1.0% of hydrocortisone appeared in the urine over 10 days after topical application of C-14 radiolabelled hydrocortisone to normal skin.

Biotransformation

Hydrocortisone is metabolised in the liver most likely by reduction of the 5, 6 double bond and the C3 and C20 keto groups. The resultant hydroxy derivatives are then conjugated with glucuronic acid. Cortisone, an 11-keto-steroid is formed from hydrocortisone; the 11-keto-steroids are then reduced and conjugated to yield glucuronide metabolites. A small percentage of hydrocortisone is converted to the 17-keto-steroid. The C21 hydroxyl group is conjugated with sulphate.

Elimination

When radioactive-carbon, ring-labelled steroids are injected intravenously in man, most of the radioisotope is recovered in the urine within 72 hours. Neither biliary nor faecal excretion is of any quantitative importance in man. It has been estimated that the liver metabolises at least 70% of the hydrocortisone secreted.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Phenoxyethanol
White soft paraffin
Liquid paraffin
Ceteareth-20
Cetostearyl alcohol
Purified water

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

24 months

6.4. Special precautions for storage

Store below 30 °C.

6.5. Nature and contents of container

Aluminium tube with white plastic cap.
30 g

6.6. Special precautions for disposal

No special requirements for disposal.

7. MEDICINE SCHEDULE

Pharmacist Only Medicine

8. SPONSOR

AFT Pharmaceuticals Ltd
Level 1, 129 Hurstmere Road
Takapuna
Auckland, 0622

Phone: 0800 423 823
Email: customer.service@aftpharm.com

9. DATE OF FIRST APPROVAL

05 June 2020

10. DATE OF REVISION OF THE TEXT

28 March 2022