New Zealand Data Sheet

1 Hydrocortisone Cream 1% (AFT)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Hydrocortisone Cream 1% (AFT) contains hydrocortisone acetate 1%.

For the full list of excipients, see **Section 6.1**.

3 PHARMACEUTICAL FORM

Hydrocortisone Cream 1% (AFT) is a smooth white viscous cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Hydrocortisone is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses.

4.2 Dose and method of administration

A thin film should be applied to the affected area three to four times daily.

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

4.3 Contraindications

Hydrocortisone is contraindicated in patients with a history of hypersensitivity to the product or any of its constituent ingredients, patients with tuberculosis or fungal infection and/or herpes infections of the eyes, lips, or genitals.

4.4 Special warnings and precautions for use

Although extensive use of hydrocortisone has not revealed evidence that enough hydrocortisone is absorbed to have systemic effects, greater absorption because of misuse or individual variability or unusual sensitivity could lead, at least theoretically, to a systemic effect.

Patients are advised to contact their physician if the condition under treatment worsens or if symptoms persist for more than seven days or if symptoms clear and occur again within a few days.

Hydrocortisone is not recommended for use in children under two years of age.

Hydrocortisone should not be used for external feminine itching if a vaginal discharge is present. It is not to be used for external anal itching if bleeding is present.

Contact with the eyes should be avoided.

Hydrocortisone should not be used under waterproof dressings unless advised to do so by a physician.

Hydrocortisone should not be used to treat acne.

If the product is applied with the fingertips, hands should be washed afterwards.

Visual disturbance

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, consider evaluating for possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

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

The safety of this medicinal product for use during human pregnancy or during lactation has not been established.

Breast-feeding

Hydrocortisone should only be used during pregnancy or lactation if recommended by a physician.

Fertility

No data on fertility 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

The safety profile of topically applied hydrocortisone preparations has been established through over 40 years of marketing experience. Topically applied hydrocortisone generally does not produce systemic effects due to minimal absorption. Absorption increases in the presence of skin inflammation or with the use of occlusive agents. Certain local effects such as skin atrophy may arise with prolonged use because of the antimitotic/antisynthetic effect of hydrocortisone on cells. Clinically detectable atrophy rarely occurs with hydrocortisone in concentrations available without prescription (0.5%, 1.0%).

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

There is no specific overdosage syndrome associated with the use of topical hydrocortisone. No specific antidote is available. Treatment of acute oral overdose consists of dilution with fluids.

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

5 PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Corticosteroid

ATC group: D07AA02

5.1 Pharmacodynamic properties

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

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 to 12 hours. Biotransformation takes place primarily in the skin, and for any amount absorbed systematically, in the liver. 0.2% to 1.0% of hydrocortisone appeared in the urine over 10 days after topical application of C-14 radiolabelled hydrocortisone to normal skin.

5.3 Preclinical safety data

There are no preclinical safety data of relevance to the prescriber which are additional to those included in other sections.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Cetostearyl alcohol
- Propylene glycol
- Purified water
- Sodium laurilsulfate
- White soft paraffin

6.2 Incompatibilities

In the absence of compatibility studies, this medicine must not be mixed with other medicines.

6.3 Shelf life

15g Tube: 60 months from date of manufacture

30g Tube: 48 months from date of manufacture

6.4 Special precautions for storage
Stored at or below 25°C

6.5 Nature and contents of container
Both 15g and 30g Hydrocortisone Cream 1% (AFT) are supplied in aluminium, laminate tubes.

6.6 Special precautions for disposal
No special requirement for disposal

7 MEDICINE SCHEDULE
Restricted Medicine

8 SPONSOR
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11 March 1999

10 DATE OF REVISION OF THE TEXT
28 March 2022

SUMMARY TABLE OF CHANGES

Sections Changed	Summary of new information
4.2	Corticosteroids – rebound effect
4.8	Corticosteroids – rebound effect