

SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT:

- 1.1 Brand Name : **Cortileb Cream**
1.2 Generic Name : Hydrocortisone Acetate Cream USP_
1.3 Strength : Hydrocortisone Acetate USP 1 % w/w
1.4 Pharmaceutical Form : Cream

2. QUALITATIVE & QUANTITATIVE COMPOSITION:

Hydrocortisone Acetate	USP	1 % w/w
Methyl Paraben	BP	0.2 % w/w
Propyl Paraben (as preservative)	BP	0.1 % w/w
Cream base		q.s

3. PHARMACEUTICAL FORM

Topical Cream
White coloured, smooth perfumed cream.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Hydrocortisone Acetate (**Cortileb**) cream is indicated for mild inflammatory skin disorders such as eczemas, allergic contact dermatitis, irritant dermatitis and insect bite reactions, nappy rash.

4.2 Posology and method of administration

To be applied sparingly over the affected skin area.

Mild inflammatory skin disorders such as eczemas, allergic contact dermatitis, irritant dermatitis, and insect bite reactions: **Child:** Apply 1–2 times a day, to be applied thinly. **Adult:** Apply 1–2 times a day, to be applied thinly.

Nappy rash: **Child:** Apply as required for no more than 1 week, discontinued as soon as the inflammation subsides.

Continuous daily application of a mild corticosteroid such as hydrocortisone 1% is equivalent to a potent corticosteroid.

4.3 Contraindications

Topical corticosteroids are contra-indicated in untreated bacterial, fungal, or viral skin lesions, in rosacea, and in perioral dermatitis. Hydrocortisone is contraindicated in those patients with a history of hypersensitivity to any of the components in the preparation. They should not be used indiscriminately in pruritus (where they will only benefit if inflammation is causing the itch) and are not recommended for acne vulgaris.

4.4 Special warnings and special precautions for use

Avoid prolonged use (particularly on the face), cautions applicable to systemic corticosteroids may also apply if absorption occurs following topical and local use infection, keep away from eyes, use potent or very potent topical corticosteroids under specialist supervision in psoriasis (can result in rebound relapse, development of generalised pustular psoriasis, and local and systemic toxicity).

CSM Advice: Prescribing and Dispensing Information: When hydrocortisone cream or ointment is prescribed and no strength is stated, the 1% strength should be supplied.

Patient and Carer Advice: Medicines for children leaflet: Hydrocortisone (topical) for eczema. Patient counselling is advised for hydrocortisone cream and ointment.

Exceptions to Legal Category: Over-the-counter hydrocortisone preparations Skin creams and ointments containing hydrocortisone (alone or with other ingredients) can be sold to the public for the treatment of allergic contact dermatitis, irritant dermatitis, insect bite reactions and mild to moderate eczema in patients over 10 years, to be applied sparingly over the affected area 1-2 times daily for max. 1 week. Over-the-counter hydrocortisone preparations should not be sold without medical advice for children under 10 years or for pregnant women; they should not be sold for application to the face, anogenital region, broken or infected skin (including cold sores, acne, and athlete's foot).

4.5 Interaction with other FPPs and Other forms of Interaction

The keratolytic effect of salicylic acid facilitates the absorption of topical corticosteroids; however, excessive and prolonged use of topical preparation containing salicylic acid may cause salicylism. Concurrent administration of barbiturates, carbamazepine, phenytoin, primidone or rifampicin may enhance the metabolism and reduce the effect of corticosteroids.

4.6 Pregnancy and lactation

This drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. There is no evidence against use in lactating women. However, caution should be exercised when Hydrocortisone is administered to nursing mothers. In this event, the product should not be applied to the chest area.

4.7 Effects on ability to drive and use machines

A detrimental effect on such activities would not be anticipated from the adverse reaction profile of topical Cortileb Cream.

4.8 Undesirable effects

Rare: Adrenal suppression, Cushing's syndrome.

Frequency not known: Acne, contact dermatitis, hypertrichosis, irreversible striae atrophicae, irreversible telangiectasia, mild depigmentation (may be reversible), perioral dermatitis, side-effects applicable to systemic corticosteroids may also apply if absorption occurs following topical and local use, spread and worsening of untreated infection, thinning of the skin (may be restored over a period after stopping treatment but the original structure may never return) worsening of acne & worsening of rosacea.

Side-Effects, Further Information: In order to minimize the side-effects of a topical corticosteroid, it is important to apply it thinly to affected areas only, no more frequently than twice daily, and to use the least potent formulation which is fully effective.

4.9 Overdose & Treatment

Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage, use under occlusive dressings or misuse the features of hypercorticism may appear and in this situation topical steroids should be discontinued. There are no special procedures or antidote. Treat any adverse effects symptomatically.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-inflammatory.

Mechanism of action: Hydrocortisone is an anti-inflammatory steroid. Its anti-inflammatory action is due to reduction in the vascular component of the inflammatory response and reduction in the formation of inflammatory fluid and cellular exudates. The granulation reaction is also decreased due to the inhibition effect of Hydrocortisone on connective tissue. Stabilization of most cell granules and lysosomal membranes decreases the mediators involved in inflammatory response and reduces release of enzymes in prostaglandin synthesis. The vasoconstrictor action of Hydrocortisone may also contribute to its anti-inflammatory activity.

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5.2 Pharmacokinetic properties

Absorption: Topically applied steroids are absorbed to a significant extent only if applied to broken skin, to very large areas, or under occlusive dressings.

Distribution: Corticosteroids are rapidly distributed to all body tissues. They cross the placenta and may be excreted in small amounts in breast milk.

Metabolism: Hydrocortisone is metabolised mainly in the liver, but also the kidney, to various degraded and hydrogenated forms such as tetra-hydrocortisone.

Elimination: Hydrocortisone is excreted in the urine, mostly conjugated as glucuronides. Only very small amounts of unchanged hydrocortisone are excreted.

5.3 Preclinical safety data

None Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

SN	Ingredients	Spec.
01.	Methyl Hydroxy Benzoate (Methyl Paraben)	BP
02.	Propyl Hydroxy Benzoate (Propyl Paraben)	BP
03.	Glyceryl Monostearate	BP
04.	Stearic Acid	BP
05.	Propylene Glycol	BP
06.	Glycerin	BP
07.	Isopropyl Myristate	BP
08.	Polysorbate-40	BP
09.	Essence Rose White C8536	IH
10.	Purified Water	BP

6.2 Incompatibilities

Not Known

6.3 Shelf life

24 months

6.4 Special precautions for storage

Do not Freeze. Protect from light. Keep Out of reach of Children. Store at a temperature not exceeding 30°C.

6.5 Nature and contents of container

15gm in an aluminum lacquered collapsible tube in an inner carton.

6.6 Instructions for use and handling

Please see the package insert.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

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8. MARKETING AUTHORISATION NUMBER

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9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Nov 10, 2023

10. DATE OF REVISION OF THE TEXT

01/01/2023