SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Hydrocortisone Cream 1%

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Cream containing 1% micronised hydrocortisone

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Cream

White Cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Hydrocortisone has topical anti-inflammatory activity of value in treatment of various dermatological conditions including:

- Eczema - atopic, infantile, discoid, stasis
- Dermatitis - Primary irritant, contact allergic, photo or seborrhoeic
- Insect bite reactions
- Prurigo nodularis
- Neurodermatoses
- Otitis externa
- Intertrigo
- Napkin rash, where concurrent infection is excluded or being addressed.

Hydrocortisone cream 0.5% can be used as continuation therapy in mild cases of seborrhoeic or atopic eczema once the acute inflammatory phase has passed.

4.2 Posology and method of administration

Posology:
Adults (including elderly):
Gently apply a thin layer of cream to the affected area two or three times daily.

Children and Infants:
Gently apply a thin layer of cream to the affected area two or three times daily. Avoid prolonged use. In infants, therapy should be limited to five to seven

days.

Hydrocortisone is usually suitable for moist or weeping surfaces whereas the ointment formulation should be considered for dry, scaly or lichenified conditions.

Method of administration:
For topical application.

4.3 Contraindications

The use of hydrocortisone cream is contraindicated in the following conditions:

- Hypersensitivity to hydrocortisone or any of the other ingredients in the product.
- Untreated bacterial (e.g. impetigo), viral (e.g. herpes simplex), or fungal (e.g. candida or dermatophyte) infections.
- Scabetic Infections
- Rosacea
- Perioral Dermatitis

4.4 Special warnings and precautions for use

This product contains chlorocresol which may cause allergic reactions.

In infants and children, long-term continuous topical therapy should be avoided, as adrenal suppression can occur, even without occlusion.

Extreme caution is required in dermatoses of infancy, including napkin rash. In infants, the napkin may act as an occlusive dressing, and increase absorption. Treatment in infants should therefore be limited to five to seven days.

Appropriate antimicrobial therapy should be used whenever treating inflammatory lesions which have become infected. Any spread of infection requires withdrawal of topical corticosteroid therapy, and systemic administration of antimicrobial agents.

As with all corticosteroids, prolonged application to the face is undesirable.

Keep away from eyes.

Topical corticosteroids may be hazardous in psoriasis.

4.5 Interaction with other medicinal products and other forms of interaction

None known

4.6 Fertility, pregnancy and lactation

There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities

of foetal development including cleft palate and intra-growth retardation. There may therefore be a very small risk of such effects in the human foetus.

There is no evidence against use in lactating women. However, caution should be exercised when hydrocortisone cream 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

None known

4.8 Undesirable effects

Hydrocortisone preparations are usually well tolerated, but if any signs of hypersensitivity including allergic contact dermatitis or worsening of the original condition appear, treatment should be stopped immediately.

Epidermal thinning, telangiectasia and striae may occur in areas of high absorption such as skin folds. Skin pigmentation changes and hypertrichosis may occur after application of topical steroids.

Although less likely than with other more potent topical corticosteroids, prolonged use of large amounts or treatment of extensive areas can result in sufficient systemic absorption to produce suppression of the hypothalamic-pituitary-adrenal axis and the clinical features of Cushing's syndrome (see section 4.4). These effects are more likely to occur in infants and children, and if occlusive dressings are used. In infants the napkin may act as an occlusive dressing.

Striae may occur in intertriginous areas.

4.9 Overdose

Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse the features of hypercorticism may appear and in this situation topical steroids should be discontinued.

There are no special procedures or antidotes. Treat any adverse effects symptomatically.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Hydrocortisone is an anti-inflammatory steroid. Its anti-inflammatory action is due to reduction of the vascular component of the inflammatory response and reduction of the formation of inflammatory fluid and cellular exudates. The granulation reaction is also decreased due to the inhibition effect of hydrocortisone on connective tissue. Stabilisation of most cell granules and

lysomal membranes decreases the mediators involved in inflammatory response and reduces release of enzymes involved in prostaglandin synthesis. The vasoconstrictor action of hydrocortisone may also contribute to its anti-inflammatory activity.

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 tetrahydrocortisone.

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

Adverse effects of hydrocortisone are due to its effects on electrolyte balance, metabolism and particularly adrenal suppression. Topical use of hydrocortisone has only rarely been associated with systemic side effects.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetomacrogol Emulsifying Wax
Chlorocresol
Liquid Paraffin
Macrogol 300
White Soft Paraffin
Purified Water

6.2 Incompatibilities

None known

6.3 Shelf life

60 Months

6.4 Special precautions for storage

Do not store above 25ºC

6.5 Nature and contents of container

A collapsible aluminium tube, with a membrane seal at the nozzle, internal epoxy lacquer, latex endseal band in the crimp seal area and a white plastic cap for re closure after piercing membrane.

Pack Size 10g, 15g, 30g and 50g.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special precautions are required.

7. MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 13606/0182

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

13/09/2011

10 DATE OF REVISION OF THE TEXT

27/04/2017