SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Hydrocortisone Ointment 1 %

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ointment containing 1% micronised hydrocortisone

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Ointment

Smooth off white translucent ointment

4.1 Therapeutic Indication

Hydrocortisone has topical anti-inflammatory activity of value in the treatment of a wide variety of dermatological conditions, including the following:
eczema – atopic, infantile, discoid, stasis
dermatitis- primary irritant, contact allergic, photo or seborrhoeic
prurigo nodularis
neurodermatoses
otitis externa
intertrigo
insect bite reactions
napkin rash, where concurrent infection is excluded or being addressed.

Hydrocortisone ointment 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

Apply, once to four times daily gradually increasing the intervals between applications as the condition improves. Treatment may then be reduced to two to three times a week or when symptoms recur. Gentle massage assists penetration.

Children and infants - gently apply a thin layer of ointment to the affected area(s) two or three times a day. Avoid using for more than five to seven days at a time.

4.3 Contra-Indications

Bacterial (e.g. impetigo), viral (e.g. Herpes simplex) or fungal (e.g. candidal or dermatophyte) infections of the skin.

Hypersensitivity to any of the ingredients

Scabetic infections

Rosacea

Perioral dermatitis

4.4 Special Warnings and Special Precautions for the use

There is no good evidence that topical corticosteroids are efficacious against immediate (Type 1) allergic skin reactions or short-lived weal and flare reactions from other causes.

Topical corticosteroids are ineffective in granulomatous conditions and other inflammatory reactions involving the deeper regions of the dermis.

Topical corticosteroids are not generally indicated in psoriasis excluding widespread plaque psoriasis provided that warnings are given.

Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses following development of tolerance, risk of generalised pustular psoriasis, and local and systematic toxicity due to impaired barrier function of the skin. Careful patient supervision is important.

Although generally regarded as safe, even for long-term administration in adults, there is potential for overdosage in infants and children.

Extreme caution is required in dermatoses of infancy especially napkin eruption where the napkin can act as an occlusive dressing and increase absorption. In infants and children, courses of treatment should therefore not normally exceed 5 to 7 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 a systemic administration of antimicrobial agents.

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

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

Keep away from the eyes.

4.5 Interaction with other medicinal products and other forms of interaction

None known

4.6 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 ointment 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.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

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

ATC Code: D07AA02

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

Wool Fat

Liquid Paraffin

White Soft Paraffin

6.2 Incompatibilities

None known

6.3 Shelf life

60 Months

6.4 Special precautions for storage

Do not store above 25^0 C

6.5 Nature and Content 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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Trading as: Co-pharma

8 MARKETING AUTHORISATION NUMBER(S)

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13/09/2011

10 DATE OF REVISION OF THE TEXT

27/04/2017