SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Hydrocortisone Cream 1%

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Cream containing 1% micronised hydrocortisone

Excipient(s) with known effect

Chlorocresol

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream

White Cream

4 CLINICAL PARTICULARS

4.1 Therapeutic Indication

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.

4.2 Posology and method of administration

Posology

To be applied evenly and sparingly two or three times daily.

Adults and the elderly
The same dose is used for adults and the elderly, as clinical evidence would indicate that no special dosage regimen is necessary in the elderly.

Children
Long term therapy should be avoided where possible.

Infants
Therapy should be limited if possible to a maximum of seven days.

Method of administration

For topical application.

4.3 Contraindications

- Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.
- Untreated bacterial (e.g impetigo), viral (e.g. herpes simplex), or fungal (e.g candida or dermatophyte) infections of the skin.
- Infected lesions.
- Ulcerative conditions.
- Rosacea.
- Perioral dermatitis or acne.

4.4 Special warnings and precautions for use

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, the patient should be considered for referral to an ophthalmologist for evaluation of 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.

Remarks on indications

1. 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.

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

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

In infants and children long-term treatment should be avoided especially on the face as adrenal suppression can occur.

Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses following development tolerance, the risk of generalised pustular psoriasis and local and systemic 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 adverse effects if overused in infancy. Extreme caution is required in the dermatoses of infancy including napkin eruption. In such patients, courses of treatment should not normally exceed seven days.

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

In infants and children particularly, care should be taken that the lowest strength of hydrocortisone cream that is clinically effective is used. The 2.5% strength is normally only necessary in the more severe cases and is better avoided in infants.

The use of an occlusive dressing can considerably increase the degree of systemic absorption.

As with all corticosteroids, application to the face may damage the skin and should be avoided. Caution should be taken to keep away from the eyes.

Hydrocortisone Cream contains Chlorocresol which may cause allergic reactions.

Healthcare professionals should be aware that if the product comes into contact with dressing, clothing and bedding, the fabric can be easily ignited with a naked flame. Patients should be warned of this risk and advised to keep away from fire when using this product.

4.5 Interaction with other medicinal products and other forms of interaction

None known

4.6 Fertility, pregnancy and lactation

Pregnancy

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-uterine growth retardation. Therefore there may be a small risk of such events to the human foetus. There is a theoretical risk of such effects on the human foetus.

Breast-feeding

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. There is theoretical risk of infant adrenal function impairment if maternal systemic absorption occurs.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Treatment with hydrocortisone ointment is usually well tolerated but treatment should be stopped immediately if symptoms of hypersensitivity occur.

Epidermal thinning, telangiectasia and striae may occur in areas of high absorption such as skin folds, the face and where occlusive dressings are used. Local atrophic changes may occur in intertriginous areas or in nappy areas in young children where moist conditions favour hydrocortisone absorption.

Following prolonged topical use systemic absorption from sites may be sufficient to produce hypercorticism and suppression of the pituitary adrenal axis after prolonged treatment. This effect is more likely to occur in infants and children and if occlusive dressings are used or large areas of skin are treated.

Eye disorders:
Frequency Not known: Vision, blurred (see also section 4.4).

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; website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Excessive use under occlusive dressings may produce adrenal suppression.

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

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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids, weak (group I), ATC code: D07A A02.

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 25^0 C

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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13/09/2011

10 DATE OF REVISION OF THE TEXT

22/02/2018