SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Hydrocortisone 0.5% m/m Ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Hydrocortisone 0.5% m/m

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ointment

A white translucent ointment.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

Mild inflammatory skin disorders for topical application.

Eczema including, atopic, infantile, discoid and stasis eczema, prurigo nodularis, neurodermatoses, seborrhoeic dermatitis and contact sensitivity reactions.

Not to be used in inflammatory conditions due to infection.

4.2. Posology and Method of Administration

A small amount to be applied to the affected area evenly and sparingly two or three times daily.

ADULTS AND 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 and where possible limited to five to seven days.

4.3 Contraindications

Should not be used if allergic to hydrocortisone or to any of the excipients listed in section 6.1 or on untreated bacterial (e.g. impetigo) , fungal (e.g. candida or dermatophyte) or viral (e.g. herpes simplex) infections of the skin, infected lesions, ulcerative conditions, rosacea, peri-oral 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 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 ointment 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.

Instruct patients not to smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard.
Washing clothing and bedding may reduce product build-up but not totally remove it.

Long term continuous or inappropriate use of topical steroids can result in the development of rebound flares after stopping treatment (topical steroid withdrawal syndrome). A severe form of rebound flare can develop which takes the form of a dermatitis with intense redness, stinging and burning that can spread beyond the initial treatment area. It is more likely to occur when delicate skin sites such as the face and flexures are treated. Should there be a reoccurrence of the condition within days to weeks after successful treatment a withdrawal reaction should be suspected. Reapplication should be with caution and specialist advise is recommended in these cases or other treatment options should be considered.

4.5. Interactions with other Medicinal Products and other Forms of Interaction

No clinically significant interactions known

4.6. Fertility, pregnancy and Lactation

There is inadequate evidence of the 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.

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

4.7. Effects on Ability to Drive and Use Machines

No or negligible influence.

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, telangectasia 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.

Skin and Subcutaneous Tissue Disorders Not known (cannot be estimated from available data)
Withdrawal reactions - redness of the skin which may extend to areas beyond the initial affected area, burning or stinging sensation, itch, skin peeling, oozing pustules. (see section 4.4)
Eye disorders:
Frequency Not known: Vision, blurred (see also section 4.4 'special warnings and precautions for use').

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, 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. No special procedures or antidote. Treat any adverse effects symptomatically.
Acute overdosage is very unlikely to occur. 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

D07A A02 Corticosteroids, weak.

Mild topical corticosteroid.

5.2. Pharmacokinetic Properties

a) General characteristics and *b) Characteristics in patients:* Hydrocortisone is absorbed through the skin. It is metabolised by the liver and kidney and excreted in the urine.

5.3. Preclinical Safety Data

No data of relevance to the prescriber, which is additional to that included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

White Soft Paraffin

6.2. Incompatibilities

Not Applicable.

6.3. Shelf Life

3 years.

6.4. Special Precautions for Storage

Store in a cool place.

6.5. Nature and Content of Container

Internally-lacquered aluminium tube fitted with a polythene cap (15g).

White polystyrene jar with polystyrene cap containing polythene liner (50g).

Polypropylene jar with polythene lid (200g).

Not all pack sizes may be marketed.

6.6. Special Precautions for Use, Handling and Disposal

Apply using barrier gloves, if not available - wash hands after application.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

TEVA UK Limited,
Brampton Road, Hampden Park,
Eastbourne, East Sussex, BN22 9AG

8. MARKETING AUTHORISATION NUMBER

PL 00289/0756

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

30 March 2006

10. DATE OF REVISION OF THE TEXT

13/09/2021
POM