SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Hydrocortisone 1% Topical cream.

Axcel hydrocortisone cream.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains 1.00% w/w Hydrocortisone Ph. Eur.

Excipients with known effect: cetostearyl alcohol and chlorocresol

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Topical cream.

White coloured, water miscible cream

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Hydrocortisone has topical anti-inflammatory activities of value in the treatment of various dermatological conditions including:
• Eczema- atopic, infantile, discoid or 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 cream 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

Hypersensitivity 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

The use of an occlusive dressing can considerably increase the degree of systemic absorption. If the treatment continues longer than two weeks, the risk of systemic side effects will increase especially in children.

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.

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.

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, application to the face may damage the skin and should be avoided. Prolonged application to the face is undesirable.

Caution should be taken to keep away from the eyes.

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.
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.

Paediatric population

In infants and children particularly, care should be taken that the lowest strength of hydrocortisone cream that is clinically effective is used. Long-term continuous topical therapy should be avoided, where possible, as adrenal suppression can occur, even without occlusion.

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 rash. In infants, the napkin may act as an occlusive dressing, and increase absorption. Treatment should therefore be limited, where possible, to a maximum of 7 days.

This product contains cetostearyl alcohol and chlorocresol amongst the excipients. Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis). Chlorocresol may cause allergic reactions. Treatment with hydrocortisone cream should be discontinued if either of these reactions develops.

4.5 Interactions with other Medicaments and other forms of Interaction

No interactions have been reported for topical hydrocortisone.

4.6 Fertility, pregnancy, and lactation

Pregnancy
There is inadequate evidence of safety in human pregnancy. Topical administration of topical corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intra-uterine growth retardation. There may therefore be a very small risk of such effects in 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

Hydrocortisone does not affect the ability to drive and use machines.

4.8 Undesirable effects
Hydrocortisone preparations are usually well tolerated but if signs of hypersensitivity appear, application should be stopped immediately.

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 where skin folds are involved, or in areas such as the nappy area in small children, where constant moist conditions favour the absorption of hydrocortisone. Sufficient systemic absorption may also occur in such sites to produce the features of hypercorticism and suppression of the HPA 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).

Skin and Subcutaneous Tissue Disorders:
Frequency Not known: 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).

There are reports of pigmentation changes and hypertrichosis with topical steroids. Contact dermatitis may also occur.

Exacerbation of symptoms may occur.

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 e-PV desktop applications (https://drive.google.com/file/d/16hwTz0587ZWtSWadbBAMwQPOD_KSExZP/view) or search for e-PV Mobile applications on 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

Pharmacotherapeutic classification: 14.2.1 Topical corticosteroids: Plain.

Hydrocortisone is the main glucocorticoid secreted by the adrenal cortex. It is used topically for its anti-inflammatory effects, mediated by the reduction of formation, release and action of the various vasoactive chemicals released during inflammation. Thus producing suppression of the clinical manifestations of the disease in a wide range of disorders where inflammation is a prominent feature.

5.2 Pharmacokinetic properties

Absorption
Hydrocortisone is absorbed through skin, particularly in denuded areas.

Distribution
Corticosteroids are rapidly distributed to all body tissues. They cross the placenta to varying degrees and may be excreted in small amounts in breast milk. Corticosteroids in the circulation are usually extensively bound to plasma proteins, mainly to globulin and less so to albumin.

Metabolism
Hydrocortisone is metabolised in the liver and most body tissues to hydrogenated and degraded forms such as tetrahydrocortisone and tetrahydrocortisol.

Excretion
The metabolites are excreted in the urine mainly conjugated as glucuronides, together with a very small proportion of unchanged hydrocortisone.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients

Cetostearyl alcohol (Dehydag Wax "0")
Macrogol Cetostearyl Ether (Cremophor A6)
chlorocresol
Liquid Paraffin
Propylene Glycol
Sodium Dihydrogen Phosphate Anhydrous
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf-life

24 months.

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of container

Lacquered aluminium tube with polyethylene screw caps. Pack size: 15g

6.6 Instructions for use/handling

Not applicable.

7. APPLICANT

Kotra Pharma (M) Sdn Bhd
1, 2 & 3 Jalan TTC 12,
Cheng Industrial Estate,
75250 Melaka, Malaysia.

8. MANUFACTURER

Kotra Pharma (M) Sdn Bhd
1, 2 & 3 Jalan TTC 12,
Cheng Industrial Estate,
75250 Melaka, Malaysia.

9. REGISTRATION DETAILS

Zimbabwe registration number: 2023/14.2.1/6374

Zimbabwe category for distribution: Pharmacy Medicines (P.)

10. DATE OF REVISION OF THE TEXT

May 2023