SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Hydrocortisone 1 % w/w topical cream
Hydrocortisone cream BP 1 % w/w

2. Qualitative and quantitative composition

Each gram of cream contains 10.5 mg of hydrocortisone.

Excipient with known effect
Each gram of cream **also** contains 1 mg of chlorocresol and 76 mg of cetostearyl alcohol (see section 4.4).

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Cream.

White to off-white 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.

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
Topical use.

4.3 Contraindications
- Hypersensitivity to the active substance or 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.
- Scabetic infections.
- Rosacea.
- Perioral dermatitis.
- Infected lesions.
- Ulcerative conditions.

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 several 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.

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 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 among 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.

Excipients
This cream contains **chlorocresol**. Chlorocresol may cause allergic reactions.

This cream **also** contains **cetostearyl alcohol**. Cetostearyl alcohol may cause local skin reactions (e.g., contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interaction
No interaction studies have been studied.

4.6 Fertility, pregnancy and breastfeeding

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. There may therefore be a very small risk of such effects in the human foetus.

Lactation
There is no evidence against its use in lactating women. However, caution should be exercised when administered to nursing mothers. In this event, the product should not be applied to the chest area.
There is a theoretical risk of infant adrenal function impairment if maternal systemic absorption occurs.

4.7 Effects on the ability to drive and use machines
The medication has no or negligible influence on the ability to drive or use machinery.

4.8 Undesirable effects

- Hydrocortisone preparations are usually well tolerated but if signs of hypersensitivity appear, application should be stopped immediately.
- 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 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 if occlusive dressings are used or large areas of skin are treated.
- There are reports of pigmentation changes and hypertrichosis with topical steroids. Contact dermatitis may also occur.
- Eye disorders:
  Frequency Not known: Vision, blurred (see also section 4.4).
- 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
Pharmacological classification: 14.2.1 Topical corticosteroids: plain.

Mechanism of action
The mechanism of the anti-inflammatory activity of topical corticosteroids is unclear. Various laboratory methods including vasoconstrictor assays, are used to compare and predict potencies and/or clinical efficacies of the topical corticosteroids. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in humans.

5.2 Pharmacokinetic properties

Absorption
Hydrocortisone is absorbed through the 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
After topical administration, hydrocortisone is metabolized primarily in the skin. The small amount absorbed into the systemic circulation is metabolized primarily in the liver to inactive compounds.

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
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
Sodium acid phosphate
Chlorocresol
Polyethylene glycol hexadecyl ether
Cetostearyl alcohol
Liquid paraffin
White petroleum jelly
Polyethylene glycol
Purified water

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 months.

6.4 Special precautions for storage
Store below 30°C.

6.5 Nature and contents of the container
The cream is packed in polyethylene (copolymer and special polythene)/in an aluminium foil laminated tube.

Fill weight: 15 g.

6.6 Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. APPLICANT

Intermed
A-3, Todi Industrial Estate
Sunmill Compound, Lower Parel
Mumbai - 400013
India

8. MANUFACTURER

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No. 4, G.K. Industrial Estate, Arcot Road
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9. REGISTRATION DETAILS

Zimbabwe registration number: 2023/14.2.1/6498
Zimbabwe category for distribution: Pharmacy Medicines (P)

10. DATE OF REVISION OF TEXT

January 2024