Summary of Product Characteristics for Pharmaceutical Product

1. Name of the medicinal product

Hydromax(Hydrocortisone) Cream BP 1.0 % w/w

2. Qualitative and quantitative composition

Hydrocortisone BP 1.0 % w/w Cream Base

3. Pharmaceutical form

A white soft homogeneous cream.

4. Clinical particulars

4.1. Therapeutic indications

Hydromax 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 seborrheic.
• Insect bite reactions • Prurigo nodularis
• Neurodermatoses
• Otitis externa
• Intertrigo
• Napkin rash, where concurrent infection is excluded or being addressed.
Hydrocortisone Cream 1% W/W can be used as continuation therapy in mild cases of seborrheic or atopic eczema once the acute inflammatory phase has passed.

4.2. Posology and method of administration:

• 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.
Route: For external application only.

4.3. Contraindications:

Hypersensitivity to hydrocortisone or any of the other ingredients in the product. Untreated bacterial (e.g. impetigo), viral (e.g. herpes simplex), or fungal (e.g. candida or dermatophyte) infections.
Scabetic infections.
Rosacea.
Perioral dermatitis.

4.4. Special warnings and precautions for use:

If the treatment continues longer than two weeks, the risk of systemic side effects will increase especially in children.
In infants and children, long-term continuous topical therapy should be avoided, as adrenal suppression can occur, even without occlusion.
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 in infants should therefore be limited to five to seven 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 systemic administration of antimicrobial agents.
As with all corticosteroids, prolonged application to the face is undesirable.
Keep away from the eyes.
Topical corticosteroids may be hazardous in psoriasis.
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. Interaction with other medicinal products and other forms of interaction:

None reported.

4.6. Pregnancy and lactation:

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

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:

Discontinue treatment should sensitization occur.
Application to skin folds and moist areas, or in nappy areas in young children, may cause local atrophic changes where constant moist conditions favour the absorption of hydrocortisone. Sufficient systemic absorption may occur which may lead to suppression of the HPA (hypothalamic pituitary adrenal) axis after prolonged treatment. This effect is more likely to occur in infants and children, and if occlusive dressings are used.
Changes in skin pigmentation and hypertrichosis may occur. Contact dermatitis may also occur.
Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9. Overdose

Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage, use under occlusive dressings or misuse the features of hypercorticism may appear and in this situation topical steroids should be discontinued.

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

5. Pharmacological properties:

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Weak dermatological corticosteroid (group 1). 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 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 metabolized 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:

Not Applicable

6.1. List of excipients

Cetomacrogol 1000 Cetostearyl Alcohol White Soft Paraffin Sodium Acid Phosphate Chlorocresol

Light Liquid Paraffin Purified Water

6.2. Incompatibilities

Not Applicable

6.3. Shelf life

36 months

6.4. Special precautions for storage

Store at temperature not exceeding 30°C.

6.5. Nature and contents of container

15 gm lami tube packed in inner carton along with the leaflet.

6.6. Special precautions for disposal

Not Applicable

7. Marketing Authorization Holder:

KREMOINT PHARMA PVT. LTD.
B-8, Additional Ambernath MIDC, Ambernath (E),
Dist: Thane-421 506, India.

Manufacturing site address
KREMOINT PHARMA PVT. LTD.
B-8, Additional Ambernath MIDC, Ambernath (E),
Dist: Thane-421 506, India.

8. Marketing authorization number(s)

CTD8588

9. Date of first authorization / renewal of authorization

23/02/2024

10. Date of revision of the text

Novemeber,2024