SUMMARY OF PRODUCT CHARACTERSTICS

DROXIDERM CREAM (HYDROCORTISONE ACETATE 10 MG/G CREAM)

Droxiderm 10 mg/g cream

Summary of Product Characteristics | Y.S.P. Industries (m) SDN BHD

1. Name of the medicinal product

Hydrocortisone acetate 10mg/g Cream

2. Qualitative and quantitative composition

1g of Cream contains 10mg Hydrocortisone acetate.
For excipients, see 6.1.

3. Pharmaceutical form

A white to off-white color cream

4. Clinical particulars

4.1 Therapeutic indications

For the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

4.2 Posology and method of administration

Method of Administration

A small amount should be applied topically, twice daily.
To be used as directed by the physician.

4.3 Contraindications

The drug is contraindicated in patients who have shown hypersensitivity to hydrocortisone acetate and any other ingredients of the preparation listed in Section 6.1.
Contraindicated in primary bacterial, viral and fungal diseases of the skin and secondarily infected eczemas or intertrigo.

4.4 Special warnings and precautions for use

a) Avoid contact with eyes. Discontinue use if irritation or rashes occur. It should not be used in weeping surfaces. Caution should be exercised when used in children. In infants or children, long-term continuous therapy should be avoided. Prolonged application to the face is undesirable
b) Systemic or local therapy may increase the risk of serious or fatal infection in individuals exposed to viral illnesses such as chickenpox or measles.
c) Systemic absorption of topical corticosteroids has produced reversible hypothalamicpituitary- adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, glucosuria in some patients. This includes the application of steroids that are more potent, use over large surface area, prolonged use and the use of occlusive dressing.
d) If local irritation develops following topical corticosteroid use, the product should be discontinued.

4.5 Interaction with other medicinal products and other forms of interaction

None have been mentioned.

4.6 Fertility, pregnancy and breast-feeding

There are no adequate and well-controlled studies in pregnant women on teratogenic effect from topically applied corticosteroid. Therefore, corticosteroid should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Corticosteroid is excreted into breast milk when administered systemically. However, it is not known whether topical administration could result in detectable quantities in breast milk. Nevertheless, caution should be exercised when topical corticosteroid are administered to a nursing woman.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings, such as burning, irritation, itching, dryness, folliculitis, hypertrichosis, acneiform eruption, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, miliaria.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization 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 prepaid post, online at https://primaryreporting.who-umc.org/ET or via toll free call 8482 to Ethiopian food and drug authority (EFDA).

4.9 Overdose

No special precautions or antidotes are likely to be needed

5. Pharmacological properties

5.1 Pharmacodynamic properties

Hydrocortisone acetate, a glucocorticoid which has anti-inflammatory, antipruritic and vasoconstrictive action is effective in the treatment of various skin disorders without causing major adverse reactions compared to other more potent corticosteroids. Hydrocortisone cream increases the water binding capacity of the stratum corneum. It is combined with an emollient base that helps to retain existing skin moisture and maintains the skin in a soft and supple condition.

5.2 Pharmacokinetic properties

Hydrocortisone cream can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption of Hydrocortisone cream.
Once absorbed through the skin, hydrocortisone is handled through pharmacokinetic pathways similar to systemically administered hydrocortisone. It is metabolized primarily in the liver and is then excreted by the kidney.

5.3 Preclinical safety data

There are no preclinical safety data of relevance to the consumer

6. Pharmaceutical particulars

6.1 List of excipients

Butylated Hydroxyanisole
Butylated Hydroxytoluene
Stearic Acid
Beeswax
Cetyl Alcohol
Dimethylpolysiloxane
Mineral Oil
Propyl Paraben
Methyl Paraben
Glyceryl Monostearate
Propylene Glycol
Polysorbate 80
Triethanolamine
XanthanGum
Hydroxyethyl Cellulose
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Keep in an airtight container. Store at a temperature below 30°C and protect from light and moisture

6.5 Nature and contents of container

A standard collapsible Aluminium tube with stepped membrane
Pack sizes: Tubes of 15g

6.6 Special precautions for disposal and other handling

Keep in an airtight container. Store at room temperature below 30°C and protect from light and moisture.

7. Marketing authorisation holder

Y.S.P. INDUSTRIES (M) SDN BHD
lot 3, 5 and 7 jalan p/7, section 13, kawasan perindustian bandar baru bangi, 43000 kajang, selangor darul ehsan, Malaysia

8. Marketing authorisation number(s)

Registration No: 05881/07405/NMR/2019

9. Date of authorization

Approval date: 23-04-2021

10. Date of revision of the text

October 2022