Summary of Product Characteristics

1. Name of the medicinal product:

Betason Cream (Betamethasone Cream)

2. Qualitative and quantitative composition

Each gram contains:
Betamethasone Valerate BP
Equivalent to Betamethasone....0.10 % w/w

Excipients with known effect: Chlorocresol and Cetostearyl alcohol

For a list of excipients, see Section 6.1.

3. Pharmaceutical form

Cream (Topical)
A white homogeneous semisolid cream, free from any visible particles.

4. Clinical particulars

4.1 Therapeutic indications

Helps to reduce swelling, redness, itching and allergic reactions. Betamethasone treats skin problems that are accompanied by itching and swelling. i.e. atopic dermatitis, contact dermatitis, dermatitis herpetiformls, dermatomyositis, eczema, exfoliative dermatitis, keratitis, psoriasis, seborrheic dermatitis, urticaria.

4.2 Posology and method of administration

Posology

For topical dermatological use only. Not for ophthalmic, oral or Intravaginal use. Wash hands before and after application. Use gloves if required by universal precautions. Apply sparingly in a thin film and rub gently into affected area (S) of clean, dry skin. Restrict application to the affected areas and try to avoid normal surrounding skin. Patients who fail to respond to topical treatment after 1-4 weeks should be re-evaluated. The amount of Cream needed to cover a certain skin area can be calculated. A 1g application of Cream covers 100cm2 of skin. The entire skin surface of the average size adult will be covered by 30g of topical Cream. Topical preparations containing steroids generally should not be used with occlusive dressings. Instruct patients not to bandage cover or wrap area in any way that may be occlusive, unless directed by prescriber.

Method of administration: Topical

4.3 Contraindications

Infection, measles, tuberculosis herpes or chicken pox

- Large areas of burned or damage skin
- Skin wasting or thinning
- An unusual or allergic reaction to betamethasone, corticosteroids. other medicines, foods, dyes or preservatives.

- Pregnant or trying to get pregnant
- Breast-feeding

If you are going to use betamethasone for a long time, your prescriber or health care professional needs to know if you have:

- Diabetes
- Glaucoma or cataracts

Topical betamethasone should be used with extreme caution in patients with poor circulation due to the risk of skin ulceration because corticosteroids can inhibit wound healing, betamethasone should not be used in areas of skin abrasion.

4.4 Special warnings and precautions for use

- Infection, measles, tuberculosis herpes or chicken pox
- Large areas of burned or damage skin
- Skin wasting or thinning
- An unusual or allergic reaction to betamethasone, corticosteroids. other medicines, foods, dyes or preservatives.
- Pregnant or trying to get pregnant
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4.5 Interaction with other medicinal products and other forms of interaction

There are no known interactions between betamethasone skin preparations and other drugs.

4.6 Pregnancy and Lactation

Consult physician in below condition

- Pregnant or trying to get pregnant
- Breast-feeding

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

- Burning or itching of the skin
- Dark red spots on the skin
- Infection
- Painful, red, pus-filled blisters in hair follicles
- Thinning of the skin, sunburn more

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic https://pv.pharmacyboardkenya.org'

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 requested to report any suspected adverse reactions via the Pharmacy and Poisons Board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org.

4.9 Overdose

Symptoms and signs

Topically applied betamethasone valerate may be absorbed in sufficient amounts to produce systemic effects. Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse the features of hypercortisolism may occur.

Treatment

In the event of overdose, betamethasone valerate should be withdrawn gradually by reducing the frequency of application, or by substituting a less potent corticosteroid because of the risk of glucocorticosteroid insufficiency.

5. Pharmacological properties

Pharmacological classification: Synthetic Gulcocorticoids
ATC Code: D07AC01 Corticosteroids, potent (group III)

5.1 Pharmacodynamic properties

Betamethasone and its derivatives are synthetic glucocorticoids used anti-inflammatory or immunosuppressive agents. The drug has little mineralocorticoid activity and should be used with a mineralocorticoid to manage adrenal insufficiency. Topically Betamethasone valerate is used for treating inflammation due to corticosteroid-responsive dermatoses.

5.2 Pharmacokinetic properties

Topical preparations are administered in a thin film and rubbed gently into the affected area. Dosages of the topical preparations are expressed in terms of betamethasone. The amount of betamethasone absorbed following topical application is dependent on the state of the skin at the appllcation site. Absorption after topical application is increased in areas that have skin damage, inflammation or occlusion. There may be a small extent of systemic absorption of the topical solutions, especially via the oral mucosa. Topical preparations distribute throughout the area of application. Topical preparations of Betamethasone are

5.3 Preclinical safety data
Not applicable

6. Pharmaceutical Particulars

6.1 List of Excipients
Cetomacrogol 1000, Cetostearyl Alcohol, Heavy Liquid Paraffin, White Petroleum Jelly, Chlorocresol, Propylene Glycol, Polysorbate 80, Citric Acid, Disodium Hydrogen phosphate dihydrate, and Purified Water.

6.2 Incompatibilities
Not applicable.

6.3 Shelf-Life
36 months (3 Years)

6.4 Special Precautions for Storage
Store in well-closed container preferably below 30 °C.

6.5 Nature and Content of container
15g printed Lami tube. Single 15g filled tube packed in carton along with pack insert.

6.6 Special precautions for disposal and other handling
No special requirement

7. Marketing Authorization Holder
30th Floor, Almas Towers,
Jumeirah Lakes Towers, Dubai,
UAE.

8. Marketing Authorization Number
H97/141

9. Date of first authorization/renewal of the authorization
17 Apr 1997

10. Date of revision of the text
29/01/2025