BERLINBACT CREAM
(Clotrimazole and Betamethasone Dipropionate Cream USP)

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the Medicinal Product

BERLINBACT CREAM

Clotrimazole and Betamethasone Dipropionate Cream USP

2. Qualitative and Quantitative Composition

Composition

Clotrimazole USP 1.0 % w/w

Betamethasone Dipropionate USP

Eq. to Betamethasone 0.05% w/w

Cream Base q.s.

3. Pharmaceutical Form

Cream

4. Clinical Particulars

4.1 Therapeutic indications

Clotrimazole and Betamethasone Dipropionate Cream is indicated for the relief of the inflammatory manifestatios of corticosteroid responsive dermatoses when complicated by secondary infection caused by organism sensitive to the components of this dermatologic preparation or when the possibility of such infection is suspected.

4.2 Posology and method of administration

Dosage and Administration

A small quantity of Clotrimazole and Betamethasone Dipropionate cream should be applied to cover completely the affected area two or three times daily, or as prescribed by the physician. Frequency of application should be determined according to severity of the condition. During the therapy should be determined by patient response. In cases of tinea pedis, longer therapy should be determined by patient response. In cases of tinea pedis, longer therapy (2-4 weeks) may be necessary.

4.3 Contraindications

Clotrimazole and Betamethasone Dipropionate Cream are contra-indicated in those patients with a history known sensitivity reactionsto to any of its components.

4.4 Special warning and special precaution for use

Local and systemic toxicity is common especially following long continued use on large areas of damaged skin and in flexures. If used on the face, courses should be limited to 5 days.

Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses following the development of tolerance, risk of generalised pustular psoriasis and local and systemic toxicity due to impaired barrier function of the skin.

Any of the side effects that are reported following systemic use of corticosteroids, including adrenal suppression, manifestation of Cushing's syndrome, hyperglycemia, and glycosuria may also occur with topical steroids, especially in infants and children.

Cream is not intended for ophthalmic use.

Visual disturbance may be reported with systemic and topical (including, intranasal, inhaled and intraocular) 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 of visual disturbances 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.

4.5 Interaction with other medicinal products and form of interaction

No interaction studies have been performed.

4.6 Pregnancy and lactation

Pregnancy:

There is a limited amount of data from the use of clotrimazole in pregnant women.

Animal studies with clotrimazole have shown reproductive toxicity at high oral doses. At the low systemic exposures of clotrimazole following topical treatment, harmful effects with respect to reproductive toxicity are not predicted. Clotrimazole can be used during pregnancy, but only under the supervision of a physician or midwife.

Lactation:

Available pharmacodynamic/toxicological data in animals have shown excretion of clotrimazole/ metabolites in milk after intravenous administration. A risk to the suckling child cannot be excluded. A decision must be made whether to discontinue breastfeeding or to discontinue/abstain from clotrimazole therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

4.7 Effects on ability to drive and use machines

Clotrimazole & Betamethasone Dipropionate Cream has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse reactions reported include: burning and stinging, maculopapular rash, oedema, paraesthesia and secondary infection.

Reported reactions to clotrimazole include erythema, stinging, blistering, peeling, oedema, pruritus, urticaria and general irritation of the skin.

Reactions to betamethasone dipropionate include: burning, itching and irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hyperpigmentation, hypopigmentation, perioral dermatitis, and allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae miliaria, capillary fragility (ecchymoses), blurred vision and sensitisation.

In children receiving topical corticosteroids, Hypothalamic-pituitary adrenal (HPA) axis suppression (HPA) axis suppression, Cushing's syndrome and intracranial hypertension have been reported.

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.

4.9 Overdose

SYMPTOMS: Excessive or prolonged use of topical corticosterois can suppress pituitary adrenal function, resulting in secondary adrenal insufficiency and produce manifestations of hypercorticism including cushing disease.

Excessive or prolongeduse of topical antibiotic lead to over growth of lessions by nonsusceptible organisms.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Vasoconstrictor Assay

Studies performed with clotrimazole and betamethasone dipropionate cream indicate that these topical combination antifungal/corticosteroids may have vasoconstrictor potencies in a range that is comparable to high-potency topical corticosteroids. However, similar blanching scores do not necessarily imply therapeutic equivalence.

5.2 Pharmacokinetic properties

Topical corticosteroids can be absorbed from normal intact skin. The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier. Inflammation and/or other disease process in the skin may increase percutaneous absorption. Systemic absorption following use of topical clotrimazole preparation is very low. Estimated bioavailability is less than 0.5 % clotrimazole concentrations achieved in the epidermal layers exceed the minimal inhibitory concentrations (MICs) for almost all pathogenic fungi.

5.3 Preclinical Studies

There are no pre-clinical data.

6. PHARMACEUTICAL EXCIPIENTS

6.1 List of excipients

1. Benzyl Alcohol BP
2. Cetyl Alcohol BP
3. Cetomacrogol-1000 BP
4. White Soft Paraffin BP
5. Liquid Paraffin BP
6. Sodium Dihydrogen Phosphate BP
7. Peg-400 BP
8. Purified Water BP

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precaution for storage

Store at a temperature not exceeding 30°C. Protect from light.

6.5 Nature contents of container

30 gm Lami tube.

6.6 Instruction for use handling and disposal

No special requirements.

7. Manufacturer name

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8. Marketing Authority

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