EBERNET 1% cream

Eberconazole

1. NAME OF MEDICINE

EBERNET 1% cream

2.QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of cream contains 10 mg of eberconazole (NITRATE). See "List of excipients" in 6.1.

3. PHARMACEUTICAL FORM

Cream.

White, viscous cream.

4. CLINICAL DATA

4.1 Therapeutic indications

EBERNET 1% cream is recommended for the treatment of dermatophyte skin infections such as Tinea corporis, Tinea cruris and Tinea pedis

4.2 Dosage and method of administration

Adults

EBERNET 1% cream should be applied twice a day for four weeks. If following this treatment period no clinical improvement is observed, the diagnosis should be reconsidered.

Suitable hygiene measures should be taken to prevent possible reinfection.

Method of administration

The cream should be applied with the tips of the fingers avoiding direct contact between the tube and the infected area. A sufficient amount of cream should be applied evenly to cover the wound and surrounding areas, and gently massaged in to improve absorption. For wounds in intertriginous areas a small amount of cream should be applied to avoid maceration of the skin.

It is important to close the tube well after each application.

Children under 18

No specific research is available for this population group.

Elderly

Modification of the dosage guidelines recommended for adults is not necessary.

Renal and/or hepatic insufficiency

Modification of the recommended dosage guidelines is not necessary for adults with renal and/or hepatic insufficiency.

4.3 Contraindications

EBERNET 1% cream is contraindicated for patients with hypersensitivity to other imidazole antifungals or to any other component of this product.

4.4 Special warnings and precautions for use

EBERNET 1% cream should not be used or applied topically to mucous membranes. In the event of contact with eyes, wash immediately with plenty of water.

Occlusive dressings should not be used as they can encourage yeasts, leading to a subsequent skin irritation.

If a skin reaction suggests sensitisation or irritation due to use of EBERNET, treatment should be interrupted immediately and the necessary corrective measures established.

No specific clinical research is available regarding the use of EBERNET on children.

Warning on excipients

This product contains methyl parahydroxybenzoate which could cause allergic reactions (possibly delayed). It also contains propylene glycol, which could cause skin irritation.

4.5 Interaction with other drugs and other forms of interaction

Although no specific interactions with other drugs have been described, it is advisable not to use concomitantly with other skin preparations in order to prevent the risk of possible interactions between treatments.

4.6 Pregnancy and lactation

No sufficient data is available regarding the use of eberconazole by pregnant women. Research on animals are insufficient with regard to the effects on pregnancy, embryo and foetal development, childbirth and postnatal development (see section 5.3). Caution must be taken when prescribing the product to pregnant women.

There is no evidence as to whether eberconazole is excreted in maternal milk. Therefore, caution must be taken when prescribing it to women during the breast-feeding period.

4.7 Effects on ability to drive and use machinery

There is no evidence that EBERNET 1% cream affects the ability to drive and handle machinery.

4.8 Adverse reactions

In clinical studies carried out on EBERNET 1% cream, approximately 3% of patients experienced adverse reactions.

Adverse reactions reported on a frequent basis (>1/100 and <1/10) included erythema and pruritus in the area of application. Other skin reactions that were expressed infrequently (>1/1000 and <1/100) included: eczema, desquamation, folliculitis and pustules. All of the reactions were, in general, mild and transient.

4.9 Overdose

No cases of overdose through the skin have been observed. However, in the event of accidental ingestion and systemic exposure to eberconazole, a suitable symptomatic treatment should be applied.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group (ATC code): Antifungals for topical use (D01A C)

Eberconazole is a derivative of imidazole with antifungal activity for the skin treatment of dermatophytosis. In vitro research suggests that the nitrate eberconazole, as the other imidazoles, inhibits the synthesis of ergosterol, the basic component of the cytoplastmatic membrane, causing an alteration in its structure and function, preventing the growth of the fungus.

Eberconazole has a spectrum of antifungal activity that includes dermatophytes, yeast and other pathogenic fungi. Eberconazole presents a MIC90 of less than 1 µg/ml for the most common dermatophyte pathogens belonging to the Trichophyton and Microsporum species as well as for Epidermophyton floccosum. It has also shown activity in Candida species of yeasts from clinical isolates, notably its activity in C. glabrata (CMI90 0.1µg/ml) and C. kruseii (CMI90 0.125µg/ml).

In an open and uncontrolled clinical test, in which a single dose of EBERNET 1% cream was administered to 12 healthy volunteers, no phototoxic effects or sensitisation was observed.

In an open and uncontrolled clinical test in which the local and systemic tolerance was assessed in 16 healthy volunteers, two single doses of eberconazole 1% cream were administered at an interval of 7 days, no reactions of hypersensitivity were reported following re-exposure.

5.2 Pharmacokinetic properties

In an open and uncontrolled clinical test, EBERNET 1% cream was administered twice a day for 28 days to 12 healthy volunteers, to determine the systemic absorption after 28 days of treatment. No detectable levels of eberconazole in plasma or urine were observed (detection limits of 1.1ng/ml and 1.0ng/ml, respectively) at the end of the research period.

5.3 Preclinical safety data

Acute oral toxicity studies in rats and mice revealed an LD50 of over 900 mg/kg and 500 mg/kg of body weight in males and females, respectively. The only relevant sign of toxicity was the reduction of the male mice's testicles after doses of over 1000mg/kg.

In chronic toxicity studies in rats and dogs, which were administered eberconazole cream topically for 28 days, no significant signs of toxicity were observed at maximum doses of 400 mg/kg/day in rats and 50 mg/kg/day in dogs.

Eberconazole was not mutagenic in the Ames test or in the L5178Y mouse lymphoma cell mutagenesis assay.

6.PHARMACEUTICAL DATA

6.1 List of excipients

Methyl parahydroxybenzoate (E214)
Cetostearyl alcohol
Polyglycol esters of fatty acids C12-C20
Decyl oleate
Propylene glycol
Formaldehyde glycerine
Glycerol
Polyacrylamide
Trolamine
Purified water

6.2 Incompatibilities

None have been described.

6.3 Period of validity

4 years.

6.4 Special storage precautions

Do not store at temperatures above 30°C.

6.5 Nature and contents of packaging

Blind end aluminium tube with a screw cap.

EBERNET 1% cream is available in tubes of 30g and 60g.

6.6 Instructions for use and handling

To avoid possible contamination of the cream, it is advisable not to place the tube in direct contact with the infected area. The cream should be applied using fingers (see section 4.2). It is important to close the tube well after each application.

7.MANUFACTURING & MARKETING AUTHORISATION HOLDER

Manufacturing: Laboratorios SALVAT, S.A.
Gall, 30-36 - 08950 Esplugues de Llobregat (Barcelona) Spain
Marketing Authorisation Holder: NewBridge Pharmaceuticals FZ-LLC, P.O.Box 500618, Dubai, UAE.

8. AUTHORISATION NUMBER

65966

9.DATE OF FIRST AUTHORISATION / RENEWAL OF MARKETING AUTHORISATION

March 2004

10.DATE OF TECHNICAL SHEET APPROVAL

March 2004

THIS IS A MEDICAMENT

- A Medicament is a product, which affects your health, and its consumption, contrary to instruction, is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not, by yourself, interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of the reach of children

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