For the use of a Registered Medical Practitioner or Hospital or a Laboratory only

CRURIX

1. Generic Name

Eberconazole Cream 1% w/w

2. Qualitative and quantitative Composition:

Eberconazole Nitrate I.P.

equivalent to Eberconazole…….1.0% w/w

Cream Base ……..……..q.s.

Preservatives:

MethylParaben I.P. ……..0.1% w/w

PropylParaben I.P. ……..…..0.025% w/w

The Excipients used are Cetomacrogol, Cetostearyl Alcohol, Glyceryl Monostearate, Light Liquid Paraffin, Dimethicone, Methyl Paraben, Propyl Paraben, Propylene Glycol, Petroleum Jelly, Sodium Hydroxide.

3. Dosage form and strength

Dosage form: Cream

Strength: Eberconazole 1.0% w/w

4. Clinical particulars

4.1 Therapeutic indication

It is indicated for the treatment of Dermatophyte infection of skin such as T-corposis, T-c, T-Pedis.

4.2 Posology and method of administration

Posology

Eberconazole 1% Cream should be applied twice daily for a period of four weeks. The medication should be used for the entire treatment period, even if the symptoms may have improved. If no improvement is seen after 4 weeks, the Physician should be informed. If no clinical improvement is observed at the end of 4 weeks, the diagnosis should be reconsidered. Suitable hygiene measures should be maintained to prevent a possible recurrence of infection.

Method of administration

The Cream should be applied with the fingertips ensuring that the tube does not come into direct contact with the infected area.

The Cream should be spread evenly on the affected area and the area adjacent to it, and massaged gently to ensure penetration. For intertriginous lesions, only a small quantity of Cream should be applied to avoid maceration of the skin.

The tube should be closed firmly after use.

4.3 Contraindications

Eberconazole 1% Cream must not be used in patients with hypersensitivity to other imidazole Anti-Fungals or to any other component of this medicinal product.

4.4 Special warnings and precautions for use

Eberconazole 1% Creamis not to be used on either the eyes or the mucosa If the product comes in contact with the eyes, wash thoroughly with plenty of water. Occlusive bandages that do not transpire should be avoided as they may favour the growth of yeast and lead to irritation of the skin.

If there is any sensitization or irritation from the use of Eberconazole, the treatment should be stopped and appropriate therapeutic measures should be taken.

No specific clinical studies on the use of Eberconazole in children are available.

Use in Patients with Renal and Hepatic impairment

No dosage adjustment is required for adults with abnormal renal and hepatic functions.

Use in Elderly Patients

The recommended adult dosage does not have to be altered for the elderly.

Use in Children

The safety and efficacy of Eberconazole 1% in paediatric patients has not been established

4.5 Drugs interactions

Though no interactions with other medicinal products have been described, itis advisable not to use the product with other dermal preparations, to avoid the possible risk of interaction with drugs used in other treatments.

4.6 Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

The safety and efficacy in pregnant and lactating women has not been established

4.7 Effects on ability to drive and use machines

The effect on ability to drive and use machines has not been established.

4.8 Undesirable effects

Eberconazole is usually well tolerated. The reported side effects are of mild to moderate intensity. The most reported side effects are redness and itching at the application site. Rarely other side-effects like eczema (inflammation), exfoliation (peeling), folliculitis (inflammation of the hair follicle) and pustules have been reported. All the reactions are mild and transient.

Reporting of adverse reactions

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at: https://www.torrentpharma.com/index.php/site/info/adverse_event_reporting by reporting side effects, you can help provide more information on the safety of this medicine.

4.9 Overdose

Over dosage on topical application of Eberconazole is unreported and is unlikely.

In case of accidental ingestion or systemic exposure to Eberconazole, an appropriate symptomatic treatment should be employed.

5 Pharmacological properties

5.1 Mechanism of Action

Eberconazole is an antifungal for topical use, it is an Imidazole derivative with antifungal activity, used for the treatment of Dermatophyte (cutaneous Mycosis) infections of the skin. In-Vitro studies suggest that Eberconazole Nitrate, like the test of the Imidazoles, inhibits the synthesis of Ergosterol, a fundamental component of the fungal cytoplasmic membrane. This alters the membrane structure and functions and leads to the inhibition of fungal growth.

5.2 Pharmacodynamic properties

Eberconazole has been shown to have broad spectrum of activity in-vitro to be effective against dermatophytes, yeast and other pathogenic fungi.

No phototoxic or sensitization effects have been reported following its usage.

No hypersensitivity reactions have been reported on re-exposure.

5.3 Pharmacokinetic properties

No detectable levels of the drug are found in plasma or urine (Limit of detection, 1.1 ng/ml and 1.0ng/ml respectively) when administered to healthy volunteers after 28 days of treatment.

6 Nonclinical properties

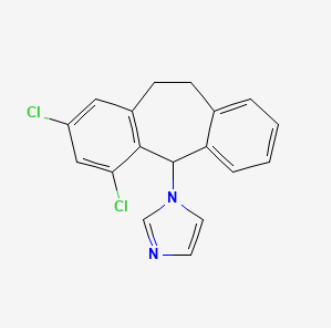
6.1 Animal Toxicology or Pharmacology

Not applicable

7 Description

Eberconazole:

Eberconazole Nitrate is (RS)-1-(2,4-Dichloro-10,11-dihydro-5*H*-dibenzo[*α,d*]-5-cycloheptenyl)-1*H*-imidazole nitrate. The empirical formula is $C_{18}H_{14}CL_2N_2,HNO_3$ and its molecular weight is 392.2 g/mol. The chemical structural formula is:



CRURIX:

Eberconazole Cream are a white coloured cream. The Excipients used are Cetomacrogol, Cetostearyl Alcohol, Glyceryl Monostearate, Light Liquid Paraffin, Dimethicone, Methyl Paraben, Propyl Paraben, Propylene Glycol, Petroleum Jelly, Sodium Hydroxide.

8 Pharmaceutical particulars

8.1 Incompatibilities

Not applicable

8.2 Shelf-life

Do not use later than date of expiry.

8.3 Packaging information

CRURIX is available in pack of 5 gm and 30 gm.

8.4 Storage and handing instructions

Do not store above 30°C.

Do not freeze.

Keep out of reach of Children.

Keep the cap tightly after use.

9 Patient Counselling Information

Package leaflet: Information for the user

CRURIX

(Eberconazole Cream 1% w/w)

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

9.1 What Crurix is and what it is used for

Crurix contains Eberconazole Cream 1% w/w.

It is used for the topical treatment of Dermatophyte (Cutaneous Mycosis) infections of the skin.

9.2 What you need to know before you take Crurix

Do not take Crurix

Eberconazole 1% Cream must not be used in patients with hypersensitivity to other imidazole Anti-Fungals or to any other component of this medicinal product.

Warnings and precautions

Eberconazole 1% Creamis not to be used on either the eyes or the mucosa If the product comes in contact with the eyes, wash thoroughly with plenty of water. Occlusive bandages that do not transpire should be avoided as they may favour the growth of yeast and lead to irritation of the skin.

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Use in Patients with Renal and Hepatic impairment

No dosage adjustment is required for adults with abnormal renal and hepatic functions.

Use in Elderly Patients

The recommended adult dosage does not have to be altered for the elderly.

Use in Children

The safety and efficacy of Eberconazole 1% in paediatric patients has not been established.

Pregnancy, breast-feeding and fertility

The safety and efficacy in pregnant and lactating women has not been established.

Driving and using machines

The effect on ability to drive and use machines has not been established.

9.3 How to apply Crurix

The Cream should be applied with the fingertips ensuring that the tube does not come into direct contact with the infected area.

The Cream should be spread evenly on the affected area and the area adjacent to it, and massaged gently to ensure penetration. For intertriginous lesions, only a small quantity of Cream should be applied to avoid maceration of the skin.

The tube should be closed firmly after use.

9.4 Possible side effects

Eberconazole is usually well tolerated. The reported side effects are of mild to moderate intensity. The most reported side effects are redness and itching at the application site. Rarely other side-effects like eczema (inflammation), exfoliation (peeling), folliculitis (inflammation of the hair follicle) and pustules have been reported. All the reactions are mild and transient.

9.5 How to store Crurix

Do not store above 30°C

Do not freeze.

9.6 Contents of the pack and other information

CRURIX content of Eberconazole Nitrate as active ingredients.

The Excipients used are Cetomacrogol, Cetostearyl Alcohol, Glyceryl Monostearate, Light Liquid Paraffin, Dimethicone, Methyl Paraben, Propyl Paraben, Propylene Glycol, Petroleum Jelly, Sodium Hydroxide.

CRURIX is available in pack of 5 gm and 30 gm.

10 Details of manufacturer

Optimus Pharma Pvt. Ltd.

At: Khasra No. 127-132,707/133 &

685/608/32, Vill. Jharmajri, Baddi,

Dist. Solan (H.P.) 173205, India.

11 Details of permission or licence number with date

Mfg. Licence. No.: L/16/1829/MNB Issued on.: 27.01.2022

12. Date of revision

NA

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

Torrent House, Off Ashram Road,

Ahmedabad-380 009, INDIA

IN/CRURIX 5 gm & 30 gm/ NOV 2023/01/PI