APPROVED
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INSTRUCTION
for medical use

CLOFAN

Composition:
active ingredient: clotrimazole;
1 g of cream contains clotrimazole 10 mg;
excipients: cetyl palmitate, cetostearyl alcohol, sorbitan monostearate, polysorbate 60, octyldodecanol, benzyl alcohol, purified water.

Pharmaceutical form. Cream.
Basic physical and chemical properties: homogeneous viscous cream of white colour.

Pharmacotherapeutic group.
Dermatological agents. Antifungal drugs for use in dermatology. Antifungal drugs for topical use. Imidazole and triazole derivatives. Clotrimazole. ATC code D01A C01.

Pharmacological properties.
Pharmacodynamics.
The mechanism of antifungal action of clotrimazole is associated with inhibition of ergosterol synthesis, that leads to structural and functional impairment to the fungal cytoplasmic membrane.
Clotrimazole has a broad antimycotic spectrum of action *in vitro* and *in vivo*, which includes dermatophytes, yeasts, moulds, etc.
Under appropriate test conditions, the MIC values for these types of fungi are in the region of less than 0.062–8.0 μg/ml substrate.
The mechanism of action of clotrimazole is fungistatic or fungicidal depending on the concentration of clotrimazole at the site of infection.
In vitro activity is limited to proliferating fungal elements; fungal spores are only slightly sensitive.
In addition to its antimycotic action, clotrimazole also acts on gram-positive microorganisms (*Streptococci/Staphylococci/Gardnerella vaginalis*), and gram-negative microorganisms (*Bacteroids*).
In vitro clotrimazole inhibits the multiplication of *Corynebacteria* and gram-positive cocci (with the exception of *Enterococci)* in concentrations of 0.5–10 μg/ml substrate.
Primarily resistant strains of sensitive fungal species are very rare; the development of secondary resistance by sensitive fungi has so far only been observed in very isolated case.

Pharmacokinetics.
Pharmacokinetic investigations after dermal application have shown that clotrimazole is minimally absorbed from the intact or inflamed skin into the human blood circulation. The

resulting peak serum concentrations of clotrimazole were below the detection limit of 0.001 mcg/ml, suggesting that clotrimazole applied topically is unlikely to lead to measurable systemic effects or side effects.

Clinical particulars.

Indications.

Dermatomycoses caused by moulds and other fungi (e.g., *Trichophyton*).
Dermatomycoses caused by yeast (*Candida*).
Skin diseases resulting from secondary infection with these fungi.
Candidal vulvitis and candidal balanitis.

Contraindications.

Hypersensitivity to the active substance or to any of the drug excipients.
Do not use the cream to treat nail or scalp infections.

Interaction with other medicinal products and other forms of interaction.

When used concomitantly with latex contraceptives, the cream may damage them and reduce their effectiveness. Patients are advised to use alternative methods of contraception for at least five days after taking this drug.

Special warnings and precautions for use.

This medicine contains cetostearyl alcohol, which may cause local skin reactions (e.g., contact dermatitis). The cream also contains benzyl alcohol, which can cause allergic reactions and mild irritation at the application site.
Patients should be warned not to smoke or go near open flames due to the risk of serious burns. Fabric (clothing, bedding, dressing material, etc.) that has come into contact with this cream burns more easily and is therefore a serious fire hazard. Washing clothes and bedding can reduce product accumulation, but does not remove it completely.

Use during pregnancy or breastfeeding.

Fertility.

No human studies of the effects of clotrimazole on fertility have been performed; however, animal studies have not demonstrated any effects of the drug on fertility.

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.

Breastfeeding.

There are no data on the excretion of clotrimazole in breast milk. However, systemic absorption is minimal after application and is unlikely to result in systemic effects. Clofan cream can be used during breastfeeding. In the case of topical application to the area of the nipples, the breast should be washed before feeding the child.

Ability to influence the speed of reaction when driving a car or other machinery.

Clotrimazole cream has no or negligible influence on the ability to drive or use machines.

Administration details and dosage.

The drug is intended for topical use.

The cream should be applied thinly 2–3 times daily and rubbed in gently. A strip of cream (½ cm long) is enough to treat an area of about the size of the hand. Treatment should be continued for at least one month for dermatophyte infections and at least two weeks for candidal infections.
If the feet are infected, they should be washed and dried, especially between the toes, before applying the cream.

Children.
There is no experience of using the drug in children.

Overdose.
No risk of acute intoxication is seen as it is unlikely to occur following a single dermal application of an overdose (application over a large area under conditions favourable to absorption) or inadvertent oral ingestion.
There is no specific antidote.
However, in the event of accidental oral ingestion, gastric lavage is rarely required and should be considered only if a life-threatening amount of clotrimazole has been ingested within the preceding hour or if clinical symptoms of overdose become apparent (e.g. dizziness, nausea or vomiting). Gastric lavage should be carried out only if the airway can be protected adequately.

Undesirable effects.
Since the data on the following undesirable effects are based on spontaneous reports, exact frequency of their occurrence is impossible to determine.
Immune system disorders: anaphylactic reaction, angioedema, hypersensitivity.
Vascular system disorders: syncope, arterial hypotension.
Respiratory system and mediastinal organs disorders: dyspnoea.
Skin and subcutaneous tissue disorders: vesicles, contact dermatitis, erythema, paraesthesia, skin peeling, pruritus, rash, urticaria, skin tingling/burning sensation.
General disorders and administration site conditions: application site irritation, application site reaction, swelling, pain.
Reporting of suspected adverse reactions.
The reporting of adverse reactions after the registration of the medicinal product is of great importance. This makes it possible to monitor the benefit/risk ratio when using this medicinal product. Medical and pharmaceutical workers, as well as patients or their legal representatives should be notified of all cases of suspected adverse reactions and lack of efficacy of the medicinal product through the Automated Pharmacovigilance Information System at the link: https://aisf.dec.gov.ua.

Shelf life.
2 years.

Storage conditions.
Store in original packing at temperature below 25 °C. Do not freeze.
Keep out of reach of children.

Package.
20 g in a tube, 1 tube in a carton box.

Conditions of supply.
Without prescription.

Manufacturer.
KUSUM HEALTHCARE PVT LTD.

Location of manufacturer and its address of business activity.
SP-289 (A), RIICO Industrial area, Chopanki, Bhiwadi, Dist. Alwar (Rajasthan), India.

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