APPROVED
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INSTRUCTION
for medical use

CLOFAN®

***Composition*:**
active substance: Clotrimazole;
1 gram of cream contains: Clotrimazole 100 mg;
excipients: Tefose-63 (polyethylene glycol-6 stearate, ethylene glycol stearate, polyethylene glycol-32 stearate); light mineral oil; cetostearyl alcohol; benzyl alcohol; buthylhydroxytoluene (E 321); polysorbate 60; sodium dihydrogen phosphate dihydrate; purified water; triethanolamine.

Pharmaceutical form. Vaginal cream.
Main physicochemical properties: white, viscous, uniform cream.

Pharmacotherapeutic group.
Antimicrobial and antiseptic agents, used in gynecology. Clotrimazole.
ATC Code: G01A F02.

Pharmacological properties.
Pharmacodynamic.
Clotrimazole is an antifungal agent of local action of imidazole derivatives group.
The mechanism of antimycotic action of clotrimazole is realized through inhibiting the synthesis of ergosterol, which leads to structural and functional impairment of cytoplasmic membrane.
Clotrimazole has a broad spectrum of antifungal activity *in vitro* and *in vivo*, acting on dermatophytes, yeast and molds.
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 of substrate.
The mode of action of clotrimazole is primarily 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.
Primarily resistant variants of sensitive fungal species are very rare. The development of secondary resistance by clotrimazole-sensitive fungi has so far only been observed in very isolated cases.
Pharmacokinetics.
Pharmacokinetic investigations after vaginal application have shown that only a small amount of clotrimazole (3–10%) is absorbed. The absorbed clotrimazole is metabolized in the liver into inactive metabolites. Therefore, the peak plasma concentrations of clotrimazole after vaginal application of a

500 mg dose were less than 10 ng/ml. This means that clotrimazole applied intravaginally does not lead to measurable systemic effects or side effects.

Clinical particulars.

Indications.

Clotrimazole vaginal cream is recommended for the treatment of candidal vaginitis.

Contraindications.

Hypersensitivity to clotrimazole or other ingredients of the drug.

Interaction with other medicinal products and other forms of interaction.

Latex contraceptives

Concomitant use of the cream in genital area with latex contraceptives (such as condom or diaphragm) may cause damage to the latter, therefore, the effectiveness of these contraceptives may decrease. Patients should be advised to use alternative contraceptive methods for at least 5 days after using this preparation.

Tacrolimus/sirolimus

Concomitant treatment with vaginal clotrimazole and oral tacrolimus (FK-506; immunosuppressant) or sirolimus may lead to increased tacrolimus/sirolimus blood plasma level. Patients should thus be closely monitored for signs and symptoms of tacrolimus/sirolimus overdosage, if necessary – by determination of the respective blood plasma levels.

Special warnings and precautions for use.

Before starting treatment with clotrimazole vaginal cream, you should consult your doctor.

You should consult your doctor if symptoms persist for longer than 7 days when using clotrimazole vaginal cream.

Clotrimazole vaginal cream can be reapplied if the symptoms of a candidiasis infection reappear 7 days after the end of therapy. However, you should consult your doctor if there have been more than two episodes of candidiasis during the last 6 months.

Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

Butylhydroxytoluene can cause local skin reactions (such as contact dermatitis) or irritation of the eyes and mucous membranes.

Fertility, 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, harmful effects with respect to reproductive toxicity are not predicted. Clotrimazole can be used during pregnancy, but only under the supervision of a physician.

During pregnancy, another clotrimazole dosage form should be used that does not require the use of an applicator.

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 lactation or to discontinue/abstain

from clotrimazole therapy taking into account the benefit of lactation for the child and the benefit of therapy for the woman.
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.

Effects on ability to drive and use machines.
Clofan®, vaginal cream has no or negligible influence on the ability to drive or use machines.

Posology and method of administration.
The cream should be administered intravaginally using the supplied applicator.
7 g of Clofan® cream (1 full applicator) is inserted as deeply as possible into the vagina, in the evening (before going to sleep) one time. The course of treatment is 1 day. A second course of therapy may be prescribed if necessary.
During menstruation, no treatment should be given. Treatment should be completed before menstruation begins. Do not use tampons, vaginal lavage, spermicides or other vaginal products when using this medicine.
Sexual intercourse should be avoided during therapy as the infection can be transmitted to a partner.

Children.
There is no data on Clofan® safe use in children under 16 years of age, therefore, it should not be used in this category of patients.

Overdose.
No risk of acute intoxication is seen as it is unlikely to occur following a single vaginal dose or application to the skin (application over a large area under conditions favorable to absorption) or inadvertent oral ingestion. There is no specific antidote.
However, in the event of accidental oral ingestion, routine measures such as gastric lavage should be performed only 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.
Skin and subcutaneous tissue: local skin reactions, including contact dermatitis.
Immune system: allergic reactions, including fainting (syncope), arterial hypotension, dyspnoea (shortness of breath), urticaria, itching.
Reproductive system and mammary glands: unpleasant sensations (itching, discomfort, burning) and clinical manifestations (irritation, peeling of skin, rash, swelling, erythema) in the genital area; pelvic pain, vaginal bleeding.
Gastrointestinal tract: abdominal pain.

Shelf life. 3 years.

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

Package.

7 g in a tube, 1 tube with applicator in carton.

Conditions of supply.
Without prescription.

Manufacturer.
KUSUM HEALTHCARE PVT LTD.

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

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