

Candiless & Candiless-V

Dermal & Vaginal Cream



Composition:

Each 1g of Candiless Dermal Cream contains Clotrimazole 10 mg.

Each 1g of Candiless- V Vaginal Cream contains Clotrimazole 20 mg.

Pharmacological Classification:

Anti-Fungal.

Intended Use (Common Use of the Drug):

Treatment of fungal skin infections, treatment of fungal infections of the vagina and vulva.

Mechanism of Action:

Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the fungal cytoplasmic membrane.

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 µg/ml, suggesting that Clotrimazole applied topically is unlikely to lead to measurable systemic effects or side effects.

Indications:

Use this medicine exactly as described in this leaflet or as directed by your doctor or pharmacist, consult your doctor if you are not sure.

Candiless Dermal Cream is used to treat fungal skin infections such as ringworm, athlete's foot, fungal nappy rash and fungal sweat rash. It is also used to relieve irritation of the vulva (external thrush) or the end of the penis, which may be associated with thrush.

Candiless Vaginal Cream is used to treat a fungal infection in the vagina and vulval area which may be associated with vaginal itching, vaginal soreness, a white odourless discharge from the vagina, and pain during intercourse.

Contraindications:

- Hypersensitivity to the active substance or to any of the excipients.

- Do not use Candiless cream to treat nail or scalp infections.

Side Effects:

- Like all medicines, this medicine can cause side effects, although not everybody gets them.

- If you are allergic to Candiless cream, stop using it and tell your doctor immediately. Signs of an allergic reaction may include: (skin rash, problems swallowing or breathing, swelling of the lips, face, throat or tongue, general weakness, feeling dizzy or fainting, nausea, a burning sensation in the skin, redness and irritation at the site of application, local edema, pain).

- Tell your doctor or pharmacist if you experience any side effects not listed in this leaflet.

Warnings & precautions:

- As with other creams, Clotrimazole Cream may reduce the effectiveness of latex contraceptives, such as male or female condoms.

- If the cream accidentally gets into your eyes or mouth, wash immediately with water and contact your doctor.

- Keep the affected skin areas clean.

- Do not share towels, bathrobes, etc. with other people as this may transmit the infection to them.

- Always wash your hands after treating the affected area to prevent the spread of infection.

Drug and Food Interactions:

Tell your doctor or pharmacist if you are using, have recently used or might use any other drugs, and for how long you will be using the drug.

No interactions have been reported for this combination with other drugs.

Pregnancy & Lactation & Fertility:

Pregnancy: Clotrimazole is very poorly absorbed after topical or intravaginal application. There are no adequate and well-controlled studies in pregnant women during the first trimester of pregnancy. This medicine should be used during the first trimester of pregnancy only if clearly needed.

Lactation: It is not known whether Candiless Cream is excreted in human milk, so caution should be exercised during breast-feeding.

Fertility: Its effect on fertility has not been studied after topical application in humans.

Effects on ability to drive and use machines:

Candiless Cream has no or negligible influence on the ability to drive or use machines.

Method of use:

Use this drug exactly as your doctor or pharmacist has prescribed it. Ask your doctor if you are not sure.

Candiless Dermal Cream:

- The cream should be applied thinly 2- 3 times daily and rubbed in gently.

- The duration of the treatment depends upon the type of infection. Generally, a minimum of two weeks is required, although up to four weeks may be necessary.

- If the feet are infected, they should be washed and dried, especially between the toes, before applying the cream.

Candiless-V Vaginal Cream:

- The cream should preferably be inserted in the evening, just before bed time, with the use of an applicator. Using it before you go to sleep will have the best effect. Continue using the cream for 3 consecutive nights.

Inform your doctor or pharmacist if you forget to apply the cream and before stopping its use.

Overdose:

Acute overdose with topical application of clotrimazole is unlikely and would not be expected to lead to life-threatening situation.

Physical Properties:

White to off-white, smooth, uniform, free from foreign matter Cream.

Storage Conditions:

Store in a cool and a dry place at a temperature below 25°C. Keep out of reach of children.

Keep tube tightly closed.

Packaging:

Each Candiless Dermal Cream carton box contains Aluminum Tube of 20 g.

Each Candiless-V Vaginal Cream carton box contains Aluminum Tube of 30 g, with an injection device.

- A medicinal product is a product which affects your health, and it's consumption contrary to instructions is dangerous for you.
- Follow strictly the doctors prescription, the method of use and the instructions of the pharmacist who sold the medication.
- The doctor and the pharmacist experts in medicine, it's benefits and risks.
- Do not repeat the same prescription without consulting your doctor.
KEEP THE MEDICATIONS OUT OF REACH OF CHILDREN
Council of Arab Health Ministers, Union of Arab Pharmacies

Reva Pharma for Pharmaceutical Industries - Idlib - Syria

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