Package leaflet: information for the patient

Clotrimazol Slavia 10 mg/g cream

Clotrimazole

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

What you find in this leaflet:

1. What is Clotrimazol Slavia and what it is used for
2. What you need to know before you take Clotrimazol Slavia
3. How to use Clotrimazol Slavia
4. Possible side effects
5. How to store Clotrimazol Slavia
6. Contents of the pack and other information

1. What is Clotrimazol Slavia and what it is used for

Clotrimazole is a broad-spectrum imidazole antifungal that penetrates the affected layers of the skin and attacks fungi. The result is the destruction of fungi and inhibition of their growth.

Clotrimazole Slavia is indicated in the treatment of cutaneous and mucous membrane mycoses caused by dermatophytes, fungi, yeasts and microorganisms such as *Malassezia furfur* and skin infections caused by *Corynebacterium minutissimum*.

These can occur, for example, in the following forms:

- fungal infections of the foot (athlete's foot), interdigital infections of the hands or feet, periungual infections (paronychia) that occur in association with nail infections;
- superinfections with pathogenic germs sensitive to clotrimazole;
- fungal infections of the skin and skin folds, cutaneous candidiasis, pityriasis versicolor (*Tinea versicolor*, erythrasma), seborrheic dermatitis microbially superinfected with germs sensitive to clotrimazole;
- infections of the labia and genital area caused by fungi (candidiasis vulvitis);
- inflammation of the glans penis and infections of the skin of the glans penis caused by fungi (candidiasis balanitis).

2. What you need to know before you use Clotrimazol Slavia

Do not use Clotrimazol Slavia:

- if you are allergic to clotrimazole or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
The cream is intended for cutaneous use only.
Do not use Clotrimazole Slavia to treat infections of the scalp or nails.
Do not apply the cream to the eyes, nose and mouth, on mucous membranes or on open wounds. If the cream accidentally comes into contact with the eyes, wash the affected area with plenty of clean water; if side effects persist, it is necessary to consult a doctor.
If irritation occurs at the application site or allergic reactions to clotrimazole occur during treatment, the treatment should be discontinued. Clotrimazole is not administered to children under 5 years of age.

Clotrimazole Slavia with other medicines
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
There are no studies on the effects of clotrimazole on fertility in humans; however, animal studies have not demonstrated any effect of clotrimazole on fertility.

Pregnancy
There are no controlled clinical studies conducted in pregnant women. It is recommended to avoid using the cream during the first trimester of pregnancy as a precautionary measure.
Breast-feeding
Breastfeeding should be discontinued during treatment with clotrimazole.

Driving vehicles and using machineries
The medicine does not affect the ability to drive and use machines.

Clotrimazol Slavia contains propylene glycol
May cause skin irritation.

Clotrimazole Slavia contains methyl p-hydroxybenzoate (E 218) and propyl p-hydroxybenzoate (E 216)
May cause allergic reactions (possibly delayed).

Clotrimazole Slavia contains cetostearyl alcohol
May cause local skin reactions (e.g., contact dermatitis).

3. How to use Clotrimazol Slavia

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Clotrimazole Slavia is administered cutaneously. Apply the cream 2-3 times a day, in a thin layer and massage gently until the cream penetrates the skin. Generally, about ½ cm of cream is sufficient for the treatment of an area the size of the palm of your hand.

For infections of the labia (candidiasis vulvitis) and adjacent areas, candidiasis balanitis and inflammation of the glans penis, apply the cream to the affected area of the skin (for example from the vagina to the anus), 1-3 times a day. For foot infections, it is recommended to wash and dry the feet, especially interdigital, before applying the cream.

The duration of treatment varies depending on the severity of the infection and its location. To ensure a complete cure, treatment should be continued as indicated below; the duration of treatment is:
- cutaneous mycoses, including athlete's foot: 3 - 4 weeks;
- erythrasma: 2 - 4 weeks;
- pityriasis versicolor: 1 - 3 weeks;
- candidal vulvitis and balanitis: 1 - 2 weeks.

Patients should consult a doctor if symptoms do not improve after 4 weeks of treatment.

To avoid new contamination and reinfection, patients should be advised to follow personal hygiene measures. Towels, clothing, and socks that come into contact with affected skin areas should be changed daily. These simple measures will improve the positive outcome of treatment and prevent the spread of infection to other areas of the skin and to other people.
Patients should inform their doctor if symptoms do not improve after 4 weeks of treatment.

If you use more Clotrimazol Slavia than you should
No case of overdose has been reported after cutaneous administration.

If you forget to use Clotrimazol Slavia
Do not apply a double amount of cream to make up for a forgotten application. Continue with the treatment regimen above or as recommended by your doctor.

If you stop using Clotrimazol Slavia
To ensure complete healing and prevent the infection from coming back, do not stop treatment sooner than necessary without talking to your doctor. If you want to stop treatment without talking to your doctor, the infection may not be completely cured. Do not stop treatment as soon as your symptoms disappear, but continue it as directed, depending on your condition.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

May occur:
Immune system disorders:

- allergic reactions (syncope, low blood pressure, difficulty breathing, hives).

Skin and subcutaneous tissue disorders:

- blisters;
- discomfort/pain;
- fluid accumulation in tissues (edema);
- irritation;
- peeling;

- itching;
- redness;
- stinging;
- burning.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system the details of which are published on the website of the National Medicines and Medical Devices Agency http://www.anm.ro/. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Clotrimazol Slavia

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the packaging after "EXP". The expiry date refers to the last day of that month.

Use this medicine before the expiry date written on the packaging.

Store at temperatures below 25ºC, in the original packaging.

Do not throw any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Clotrimazol Slavia contain

- The active substance is clotrimazole.
- The other ingredients are: cetylstearyl alcohol, polysorbate 80, methyl p-hydroxybenzoate (E 218), n-propyl p-hydroxybenzoate (E 216), white soft paraffin, propylene glycol, purified water.

What Clotrimazol Slavia looks like and contents of the pack

Clotrimazole Slavia is presented in the form of a semi-solid, homogeneous, unctuous, white colored, odorless mass.

Packaging

Box with an aluminium tube of 20 g of cream.

Marketing Authorization Holder and Manufacturer

Marketing Authorization Holder

S.C. Slavia Pharm S.R.L.
44C Theodor Pallady Bvd,
3rd District, Bucharest, Romania

Manufacturer

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