

Package leaflet: information for the patient**Miconazol Slavia 20 mg/g cream**

Miconazole nitrate

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

- Keep this leaflet. You may need to re-read it.
- If you have any additional questions, ask your doctor or your pharmacist.
- This medicine has been prescribed only for you. You must not give it to other people. It can harm them, even if they have the same signs of illness as you.
- If you experience any side effects, contact your doctor or pharmacist. These include any possible side effects not mentioned in this leaflet. See point 4.

What you find in this leaflet:

1. What is Miconazol Slavia 20 mg/g cream and what is it used for
2. What you need to know before using Miconazol Slavia 20 mg/g cream
3. How to use Miconazol Slavia 20 mg/g cream
4. Possible side effects
5. How to Miconazol Slavia 20 mg/g cream
6. Contents of the packaging and other information

1. What is Miconazol Slavia 20 mg/g cream and what is it used for

Miconazol Slavia 20 mg/g contains miconazole nitrate, a dermatological use antifungal agent, a derivate of imidazoles and triazoles.

It is used in the local treatment of

- Cutaneous candidiasis, of the nails or of the genital apparatus non-follicular dermatophytes (as a systemic treatment adjuvant), pityriasis vesicolor, erytrasma
- Dermo-epidermic infections with Gram-positive bacteria (*Corynebacterium minutissimum*)

2. What you need to know before using Miconazol Slavia 20 mg/g cream**Do not use Miconazol Slavia 20 mg/g cream:**

- if you are allergic to miconazole, to other imidazole derivates antifungal medicines or to any of the other ingredients of this medicine (listed in point 6).

Warnings and precautions

Before using Miconazol Slavia 20 mg/g cream, consult your doctor or pharmacist.

You must avoid contact with your eyes. If the cream gets into your eyes, rinse with water immediately. Keep your eyes open.

If an allergic reaction of any type occurs, immediately stop the administration of Miconazole Slavia and address your doctor.

Pregnancy, breastfeeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or intend to become pregnant, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

It is not advised to use Miconazol Slavia during pregnancy, only if your doctor considers it necessary.

Breastfeeding

It is not recommended the utilisation during breastfeeding unless your physician considers it is absolutely necessary.

Driving vehicles and using machineries

Miconazole does not affect the ability to drive vehicles or use machineries.

Miconazol Slavia 20 mg/g cream contains:

Cetostearyl alcohol: may cause local adverse skin reactions (as an example, contact dermatitis).

Methyl p-Hydroxybenzoate (E218), n-propyl p-Hydroxybenzoate (E216): can cause allergic reactions (even delayed.)

Propyleneglycol: can cause skin irritation.

3. How to use Miconazole Slavia 20 mg/g cream

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

Using the cream

- Each cream tube is sealed. You must use the stopper to break the seal.
- Apply the cream to the affected area and around it, only after washing your hands.
- Do not apply the cream in the area around the eyes - the cream is only applied to the skin or nails.
- Do not swallow the cream.

For skin infections

- Apply the cream twice a day - morning and evening - after washing and drying the affected area. Continue to apply the cream for at least 7 days after the signs of infection have disappeared. This will prevent the recurrence of the infection.

For nail infections

- You must cut your nails as short as possible.
- Apply the cream twice a day. Continue to apply the cream for at least 7 days after the signs of infection have disappeared. This will prevent the recurrence of the infection.

For infections of the external ear (auditory canal)

- Apply the cream twice a day on the external ear.

Personal hygiene

- Wash your hands with soap and water after using the cream, if the affected skin area is not at palm level.
- By washing your hands after using the cream, you will prevent the infection from spreading to other areas of your body.
- Do not allow other people to use your towel. This will prevent them from becoming infected.
- Clothes that come into contact with infected skin must be washed and changed often.

If you use more Miconazol Slavia 20 mg/g cream than you should

Due to the low concentration of the active substance and local administration, acute overdose is unlikely. In case of accidental ingestion, symptomatic treatment is instituted.

If you forget to use Miconazol Slavia 20 mg/g cream

Do not take a double dose to make up for a missed dose.

If you stop using Miconazol Slavia 20 mg/g cream

If you have any further questions about this medicine, address your doctor or pharmacist.

4. Possible adverse reactions

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

Stop using Miconazol Slavia if you see any of the side effects listed below and inform your doctor as quick as you can.

The following adverse reactions have been reported at the topical administration of miconazole:

Uncommon (affects less than 1 in 100 people):

- Cutaneous burning sensation
- Cutaneous swelling
- Skin discoloration
- Application site irritation
- Application site burning sensation
- Itching at the application site
- Non-specific reactions at the application site
- Application site warm sensation

Unknown frequency (cannot be estimated from the available data)

- Severe allergic reactions
- Hypersensitivity
- Angioedema
- Urticarial
- Contact dermatitis
- Transitory cutaneous eruption
- Skin reddening
- Itching

Adverse reaction reporting

If you experience any side effects, contact your doctor or pharmacist. These include any side effects not mentioned in this leaflet. You can also report adverse reactions directly through 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 additional information about the safety of this medicine.

5. How to store Miconazol Slavia 20 mg/g cream

Do not let this medicine in the sight and reach of children.

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

Store at temperatures below 25°C, in the original packaging.

Do not throw any medicine into water or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. Package contents and other information

What does Miconazol Slavia 20 mg/g cream contain

- The active substance is miconazole nitrate.
- The other components are: cetostearyl alcohol, white petrolatum, cetyl palmitate, propylene glycol, liquid paraffin, polysorbate 80, methyl p-hydroxybenzoate (E 218), n-propyl p-hydroxybenzoate (E 216), purified water.

What does Miconazol Slavia 20 mg/g cream look like and packaging contents

It presents as: semi-solid, homogenous, unctuous mass, white colored, without smell.

Box with a tube of 20 g cream

Marketing authorization holder and manufacturer

S.C. Slavia Pharm S.R.L.

44C Theodor Pallady Bvd, 3rd District, Bucharest, Romania

For any information regarding this medicine, please contact the local representative of the marketing authorization holder:

This leaflet was revised in August 2017.