

**Package leaflet: Information for the patient****Seboderm Med 20 mg/ml shampoo**  
Ketoconazole

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

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not notice any improvement or feel that the condition is getting worse.

**What is in this leaflet:**

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

**1. What Seboderm Med is and what it is used for**

Seboderm Med is a medicine that contains the active substance ketoconazole. Seboderm Med is a preparation for the treatment and prophylaxis of skin infections caused by fungi (dermatophytes and yeasts). It can be used to treat skin conditions, both on the scalp and on the body (on the face or chest). Seboderm Med is not recommended for use in children under 12 years of age.

Seboderm Med is indicated for various skin infections (mycoses) caused by fungi, which manifest themselves as:

- flaking of the scalp (dandruff);
- reddish-brown spots, accompanied by yellow or white scales, usually located on the face or chest (seborrheic dermatitis);
- small, brown or white spots on the body (*pityriasis versicolor* or *tinea versicolor*).

Seboderm Med can treat or prevent the recurrence of these infections.

**2. What you need to know before you use Seboderm Med****Do not use Seboderm Med**

- if you are allergic to ketoconazole or any of the other ingredients of this medicine (listed in section 6). Symptoms of hypersensitivity are manifested by itching or redness of the skin following use of the medicine.

**Warnings and precautions**

Talk to your doctor, pharmacist or nurse before using Seboderm Med.

- As with other shampoos, avoid contact with eyes. If this happens, rinse your eyes with plenty of cold water.
- Seborrheic dermatitis and dandruff, for which Seboderm Med is most commonly used, are usually accompanied by hair loss. Hair loss can also occur during the treatment of these conditions with Seboderm Med.

### **Other medicines and Seboderm Med**

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

In the case of treatment with dermatocorticoids (cortisone-type medications) in the form of cream, ointment or lotion, please inform your doctor or pharmacist before starting treatment with Seboderm Med.

You can start treatment with Seboderm Med, but you should not stop using the corticosteroid immediately (from the next day), because an exacerbation of the condition being treated may occur (with manifestations of redness or itching).

Continue treatment with the corticosteroid preparation as follows:

- use the same dose for the first week;
- over the next 2-3 weeks gradually reduce the frequency of application;
- after three (3) weeks you can completely discontinue the use of dermatocorticoids.

### **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 known risks associated with the use of Seboderm Med during pregnancy or breastfeeding.

### **Driving and using machines**

Seboderm Med does not affect driving and using machines.

## **3. How to use Seboderm Med**

Seboderm Med is intended for local administration, to the scalp and/or skin.

The shampoo is applied to the affected areas, previously moistened, by gently massaging until a consistent foam is obtained. For proper effectiveness, Seboderm Med must be left to act for at least 3-5 minutes, after which it is removed by thorough washing. The shampoo must also cover the scalp, not just the hair. For one wash/application, the content of the shampoo contained in the palm of your hand is sufficient.

Avoid contact of shampoo with eyes. If shampoo accidentally gets into eyes, rinse eyes thoroughly with plenty of cold water.

The frequency of use of the medicine Seboderm Med depends on the type of mycosis and the purpose of treatment (cure or prevention).

#### *Treatment:*

- Seborrheic dermatitis and dandruff (*pityriasis capitis*): twice a week for 2-4 weeks.
- *Pityriasis (tinea) versicolor*: once a day for five (5) days.

#### *Prevention:*

- Seborrheic dermatitis and dandruff (*pityriasis capitis*): once a week or once every two weeks.
- *Pityriasis versicolor*: once a day for three (3) consecutive days, before the hot season.

Always use Seboderm Med exactly as your doctor or pharmacist has told you.  
If you are not sure, ask your doctor or pharmacist.  
Seboderm Med is intended for use by adolescents over 12 years of age and adults.

#### **If you use more Seboderm Med than you should**

If the shampoo is accidentally swallowed, contact your doctor or pharmacist. In case of accidental ingestion of the shampoo, only supportive measures and relief of possible symptoms are necessary. To avoid aspiration into the lungs, vomiting should not be induced and gastric lavage should not be performed.

#### **If you forget to use Seboderm Med**

Resume use as soon as you remember. Do not take a double amount to make up for a forgotten dose.

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

#### **4. Possible side effects**

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

- *Rare side effects (may affect up to 1 in 1,000 people):*
  - inflammation of the skin follicles;
  - hair loss or changes in the texture and/or appearance of the hair;
  - skin rashes;
  - dry skin;
  - skin burning sensations;
  - application site reactions: redness, irritation, itching;
  - profuse tearing.
  
- *Very rare side effects (may affect up to 1 in 10,000 people):*
  - allergy to one of the ingredients of the medicine (listed in section 6);
  - severe reactions at the application site, including pustules (skin lesions with purulent contents);
  - acne;
  - skin peeling and other skin disorders;
  - taste changes;
  - eye irritation (redness, profuse tearing).
  
- *Side effects with not known frequency*
  - angioedema (swelling of the face and lips);
  - hives;
  - change in hair color.

#### **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:

National Agency for Medicines and Medical Devices of Romania

Aviator Sănătescu no. 48, district 1

Bucharest 011478

e-mail: [adr@anm.ro](mailto:adr@anm.ro)

Website: [www.anm.ro](http://www.anm.ro)

By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store Seboderm Med**

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 box after EXP. The expiry date refers to the last day of that month.

It does not require any special storage conditions.  
Use within 3 months of first opening the bottle.

Do not throw away any medicines 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 Seboderm Med contains**

- The active substance is ketoconazole. Each milliliter of shampoo contains 20 milligrams of ketoconazole.
- The other ingredients are: sodium lauryl ether sulfate, cocamidopropyl betaine, disodium lauryl ether sulfosuccinate, butylhydroxyanisole, tetrasodium EDTA, methyl parahydroxybenzoate, propyl parahydroxybenzoate, erythrosine (E 127), sodium chloride, trolamine or 20% hydrochloric acid solution, purified water.

### **What Seboderm Med looks like and contents of the pack**

The medicine is presented as viscous, transparent, pink shampoo.

Box with a PET (polyethylene terephthalate) bottle with a PP (polypropylene) cap containing 120 ml of shampoo.

### **Marketing Authorisation Holder and Manufacturer**

Slavia Pharm S.R.L.

Theodor Pallady Blvd. no. 44C, code 032266, Bucharest, Romania

**This leaflet was last revised in October 2023.**

Detailed information on this medicine is available on the website of the National Agency for Medicines and Medical Devices of Romania <http://www.anm.ro/>