

## PACKAGE LEAFLET: INFORMATION FOR THE USER

---

### MYCOCUR

10 mg / 1 g cream

#### TERBINAFINE

---

*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

---

*• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

---

#### What is in this leaflet?

1. What MYCOCUR is and what it is used for
2. Before you take MYCOCUR
3. How to take MYCOCUR
4. Possible side effects
5. How to store MYCOCUR
6. Further information

#### 1. WHAT MYCOCUR IS AND WHAT IS IT USED FOR

MYCOCUR is antifungal agent (antimycotic) for use on the skin. It works by killing the fungi that cause your skin problems.

MYCOCUR is used for treatment of:

- Athlete's foot (tinea pedis);
- Fungal infections of the foot (tinea pedis plantar type);
- Fungal infection of the groin (tinea cruris);
- Fungal infections on other parts of the body (tinea corporis);
- Skin candidiasis (intertrigo or rashes caused by sweating);
- Pityriasis [pityriasis (tinea) versicolor].

MYCOCUR cream has a long lasting effect. When given at the recommended doses, less than 10 of 100 people, who suffer from athlete's foot, regain infection 3 months after the start of treatment.

#### **How MYCOCUR cream works**

How can you know if you have one of the following problems:

**Athlete's foot** appears only on the feet (usually both, but not always), often between the toes. It can also appear on the top of the foot, or other parts of the sole or the foot. The most common type of athlete's foot causes cracking or peeling of the skin, sometimes with mild swelling, blisters or moist ulcers. MYCOCUR cream is recommended for athlete's foot when it occurs between the toes.

If you have a fungal infection of the nail (the fungus in and under the nail), with a change of color and structure of the nail (thick, scaly), you should consult with your doctor because MYCOCUR cream is not suitable for this type of infection. MYCOCUR tablets, available on prescription, should be used to treat nail fungus.

**Tinea cruris** (fungal infection of the groin) appears in the folds where the skin is wrinkled and, especially if they are wet, it causes itching. These are often the groin area and inner thighs where usually both sides are affected, but often one side is more affected than the other. It can be spread further, between the legs to the buttocks, or up towards the belly. It can also occur under the breasts, armpits or other wrinkled areas. This rash has a clear line, and may include blistering. It causes itching.

**Tinea corporis** can occur anywhere on the body, but it is most commonly found on the head, neck, face or hands. It usually looks like a round red rash, but it can also occur in the form of scaly spots and cause itching. Skin candidiasis (intertrigo or rash caused by sweating) also appears in the folds where the skin is wrinkled and which are wet from sweat (for example, under the breasts, armpits). It is more frequent in the elderly and obese patients or those having additional disorders such as, for example, diabetes mellitus (diabetes). It causes redness, itching and peeling.

**Pityriasis versicolor** (pityriasis) appears on the skin in form of scaly surfaces, which due to loss of pigment, become white. This is especially visible during the summer considering that the surrounding skin is normally becoming darker. It most often occurs below the neck to the waist, neck and hands, and may reoccur within months, particularly due to hot weather, and sweating.

## 2. BEFORE YOU TAKE MYCOCUR

### **Do not take MYCOCUR**

- If you are allergic (hypersensitive) to terbinafine hydrochloride or any other ingredients (see section 6).

### **Tell your doctor or pharmacist:**

- MYCOCUR cream is intended for external use only.
- Do not use MYCOCUR cream in the mouth and do not swallow it.
- If cream accidentally comes into contact with the eyes, remove it and rinse eyes thoroughly. If the discomfort persists, see your doctor.

### **Children and adolescents**

Children and adolescents under 12 years should not use MYCOCUR.

### **Taking other medicines**

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Do not use other medicines on the area treated with MYCOCUR.

### **Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

MYCOCUR should not be used during pregnancy unless necessary.

Do not use MYCOCUR during breastfeeding.

An infant must not come into contact with treated skin, including the breast.

### **Driving and using machines**

This medicine does not affect your ability to drive or use machines.

### **Other warnings**

Mycocur contains cetyl and stearyl alcohol which may cause local skin reactions (eg. Contact dermatitis).

### **3. HOW TO USE MYCOCUR**

Always take MYCOCUR exactly as indicated in this package leaflet. If you are unsure, please ask your doctor or pharmacist for advice.

If you have a fungal infection of the nail (the fungus in and under the nail), with a change of color and structure of the nail (thick, scaly), you should consult with your doctor because MYCOCUR cream is not suitable for this type of infection. MYCOCUR tablets, available on prescription, should be used to treat nail fungus.

#### **Instructions for use:**

##### **Adults**

- Before use, pierce the protective membrane of the tube using the spike at the top of the cap.
- Wash and dry the affected skin and surrounding area, and wash your hands.
- Open the tube and squeeze a small amount of cream onto your finger.
- Close the tube.
- Apply enough cream to cover the affected skin and surrounding area.
- Gently rub the cream.
- Wash your hands after touching infected skin so you do not spread the infection to yourself or transfer it to the others.

You can cover the treated area with gauze, especially at night. Use new, clean gauze after each application of cream.

#### **How often and for how long to use MYCOCUR**

Apply the cream once or twice a day to the affected area unless your doctor advises you differently:

- Athlete's foot: once a day, 1 week.
- Tinea pedis plantar type (on foot): twice a day, 2 weeks.
- Tinea cruris and tinea corporis: once a day, 1 week.
- A skin candidiasis (intertrigo or heat rash, due to sweating): once or twice a day, 1 or 2 weeks. This disease can resemble fungal diseases tinea cruris or tinea corporis. For the treatment of skin candidiasis a longer period of treatment may be necessary (2 weeks).
- Pityriasis versicolor (pityriasis): once or twice a day, 2 weeks.

Your skin should begin to repair within a few days since you start to use MYCOCUR cream. However, complete healing of damaged skin after infection withdraws will last longer, possibly up to 4 weeks. The condition usually improves within a few days, but it can deteriorate again if the cream is not applied regularly or if the application is prematurely terminated.

If you have not noticed signs of improvement 2 weeks after you have started the application of MYCOCUR cream, contact your doctor or pharmacist.

#### **To improve the treatment**

To assist the treatment, keep the affected area clean by regularly washing it. Carefully dry the area gently it touching, without rubbing. Try not to scratch, although itching may be present, as this could cause further damage and slow the healing process or spread the infection.

Since this infection can be transmitted to other people, use your own towel and clothes and do not share them with others. To protect themselves from re-infection, wash them regularly.

#### **If you forget to use MYCOCUR**

If you forget to take a dose, take it as soon as you remember. Do not take a double dose next time, but continue taking the medicine as prescribed by your doctor or as indicated in the package leaflet.

#### **If you accidentally swallow MYCOCUR**

If you or someone else swallows a certain amount of MYCOCUR cream, tell your doctor which will advise you what to do.

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.

For most of the patients the application of MYCOCUR cream is useful.

Stop using MYCOCUR cream and seek immediate medical attention if you have any of the following symptoms that could be the result of an allergic reaction:

- difficulty breathing or swallowing;
- swelling of the face, lips, tongue or throat;
- severe itching of the skin with red rash or protrusions.

#### **The following side effects have been reported:**

**Common side effects** (may occur in more than 1 in 10 people):

- peeling of the skin, itching at the application site;

**Uncommon side effects** (may occur in more than 1 in 100 people):

• damage to the skin, scabs, skin disorders, skin discoloration, redness, burning sensation, pain at the application site, irritation at the application site.

**Rare side effects** (may occur in more than 1 in 1,000 people):

- dry skin, eczema

**If MYCOCUR cream accidentally comes into contact with the eyes it may cause irritation.**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

#### 5. HOW TO STORE MYCOCUR

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 tube and carton. The expiry date refers to the last day of that month.

Do not store above 25 °C.

Shelf life: 24 months.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

#### 6. FURTHER INFORMATION

##### **What MYCOCUR contains**

The active substance is terbinafine hydrochloride.

Other ingredients are: sodium hydroxide, benzyl alcohol, sorbitan monostearate, cetyl palmitate, cetyl alcohol, stearyl alcohol, polysorbate 60, isopropyl myristate, and deionized water.

##### **What MYCOCUR looks like and contents of the pack**

MYCOCUR Cream has a light scent, it is white, slippery, and easily spreadable.

Cream is in an aluminum tube with HDPE cap with thread, in a cardboard box. Package size is 15 g.

##### **Regime of dispensing**

The medicine is issued without doctor`s prescription.

***Manufacturer***

NOBEL ILAC Sanayii ve Ticaret. A. Ő. Inkilap Mah. Akcakoca Sk. No.10; 34768 Umraniye, Istanbul, Turkey

***Manufacturer of the medicinal product***

NOBELFARMA ILAC Sanayii ve Ticaret A.Ő. Sancaklar 81100 Düzce Türkiye