

PACKAGE LEAFLET: INFORMATION FOR THE USER

MYCOCUR

10 mg / 1 g Cutaneous spray, solution

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 infection of the groin (tinea cruris);
- Fungal infections on other parts of the body (tinea corporis);
- Pityriasis [pityriasis (tinea) versicolor].

If you're not sure what is the cause of your infection, please contact doctor or pharmacist for advice before applying MYCOCUR spray.

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 spray is intended for external use only.
- Do not use MYCOCUR spray in the mouth and do not swallow it.
- Avoid contact with the face, eyes or damaged skin because of the presence of alcohol which may cause irritation. If spray accidentally comes into contact with the eyes, remove it and rinse eyes thoroughly. If the discomfort persists, see your doctor.
- Do not inhale the spray.
- MYCOCUR spray contains alcohol. Keep the bottle away from the fire.

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 solution contains propylene glycol, which can cause skin irritation.

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.

Instructions for use:

Adults

- Wash and dry the affected skin and surrounding area, and wash your hands.
- Remove the cap from the bottle.
- Before first use, press spraying pump several times until the spray goes out.
- Spray the solution in sufficient quantity to wet the affected skin and surrounding area. You can rotate the bottle in all directions and spray the solution in an attempt to access the affected area.
- Return the cap on the bottle.
- Wash your hands after using the spray. Otherwise, there is a possibility of transmission of infection to other parts of the body or to other people.

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

How often and for how long to use MYCOCUR

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

- athlete's foot: once a day for one week;
- fungal infection of the groin (tinea cruris) and fungal infections on other parts of the body (tinea corporis): once a day for one week;
- pityriasis [pityriasis (tinea) versicolor]: twice a day for one week.

Your skin should begin to repair within a few days since you start to use MYCOCUR spray. However, complete healing of damaged skin after infection withdraws will last longer, possibly up to 4 weeks.

If you have not noticed signs of improvement 2 weeks after you have started the application of MYCOCUR spray, 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 spray, tell your doctor which will advise you what to do. Alcohol contained in the spray must be taken into account.

If it accidentally comes into contact with the eyes

Rinse your eyes thoroughly. Tell your doctor if you still feel discomfort.

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. Hypersensitivity reactions to MYCOCUR are possible, which can cause swelling and pain, rash and hives. The frequency of these side effects is not known (cannot be estimated from available data).

If you experience any of these symptoms, stop using the spray and immediately contact your doctor or pharmacist.

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

Unknown (cannot be estimated from available data):

- rash

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. 1 g of MYCOCUR spray contains 10 mg of terbinafine hydrochloride (1%).

Other ingredients are: ethanol 96%, Eumulgin B2 (macrogol), propylene glycol, purified water.

What MYCOCUR looks like and contents of the pack

MYCOCUR is available in white opaque HDPE bottle with HDPE cap and spray pump in pack of 30 ml.

Regime of dispensing

The medicine is issued without doctor`s prescription.

Manufacturer

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

Manufacturer of the medicinal product

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