

EXPHAR SA	May 2019	MICOZAL – Cream
	Administrative Information and Product Information	Module 1 - Page 32 of 51

1.5.3 Patient Information Leaflet (PIL)

Name of the medicinal product
MICOZAL, cream
Ketoconazole cream 2%

Read all of this leaflet carefully before you start using 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. See section 4

In this package leaflet:

1. WHAT MICOZAL CREAM IS AND WHAT IT IS USED FOR
2. BEFORE YOU USE MICOZAL CREAM
3. HOW TO USE MICOZAL CREAM
4. POSSIBLE SIDE EFFECTS
5. HOW TO STORE MICOZAL CREAM
6. CONTENT OF THE PACK AND OTHER INFORMATION

1. WHAT MICOZAL CREAM IS AND WHAT IT IS USED FOR

This medicine is a cream for topical use

MICOZAL cream is indicated in adults for skin infections due to fungi or yeasts.

The use is intended for localized infections, on limited area of the body such as breast, back, hands, feet and groin area. Others skin infections leading to desquamation such as seborrheic dermatitis can also be treated by MICOZAL cream.

2. BEFORE YOU USE MICOZAL CREAM

Do not use MICOZAL CREAM in the following cases:

- If you have ever had an allergic (hypersensitivity) reaction to ketoconazole or to any other ingredients of the cream listed in section 6. Hypersensitivity reactions that may occur following the application of the cream are: itching, burning sensation or reddening of the skin. If this applies to you, stop using the cream and get advice from your doctor or pharmacist.
- If you are allergic to other similar antifungals or to related medicines

Warnings and precautions

- If you are applying an ointment, a cream or a lotion that contains a corticosteroid to your skin, it may be necessary for you to stop that medicine gradually (within 2-3 weeks), During that period, apply the corticosteroid in the morning and MICOZAL cream in the evening.
- Do not let the cream get into your eyes. Wash your hands carefully after each application of the cream.
- It is unadvised to use acidic pH soap because it favours the multiplication of *Candida*.

Talk to your doctor or pharmacist before using MICOZAL cream.

Other medicines and MICOZAL cream

MICOZAL cream should not be mixed with other substances.

You must systematically report any other treatment you are currently taking or have taken recently to your doctor or pharmacist.

EXPHAR SA	May 2019	MICOZAL – Cream
	Administrative Information and Product Information	Module 1 - Page 33 of 51

Pregnancy and breastfeeding:

Ask your doctor or pharmacist for advice before using this medicine if you are pregnant or breastfeeding, if you think you are or might become pregnant.

No sufficient data on the use of MICOZAL cream during pregnancy are available.

Even if there are no known risks associated with the use of MICOZAL cream in pregnancy or lactation, it is much better to ask your doctor or pharmacist for advice.

MICOZAL cream contains stearyl alcohol and cetyl alcohol

MICOZAL cream contains stearyl alcohol and cetyl alcohol. These may cause local skin reactions.

MICOZAL cream contains propylene glycol. This may cause skin irritation (for instance eczema).

3. HOW TO USE MICOZAL CREAM

MICOZAL cream is for use in adults.

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

Wash your hands carefully after applying MICOZAL cream. This is particularly important to avoid transferring the germs of the infected skin to other parts of the body or to other people.

Each tube of cream is sealed: unscrew the cap and use the cap to pierce the seal

Apply some MICOZAL cream onto the infected area and surrounding skin and rub the product gently into the skin with your fingertips.

Athlete's foot: apply the cream 2 times daily during 1 week. Rub the product gently into the skin with your fingertips. Depending on the type and extent of the infection, the treatment may last 2 to 6 weeks or an oral treatment should be considered by your doctor.

Skin localised infections, breast area, back, hands or groin area: apply the cream once daily. Rub the product gently into the skin with your fingertips. It is recommended to pursue the treatment continuously until 1 week after the complete disappearance of the lesion. Depending on the type and extent of the infection, the treatment may last 2 to 6 weeks.

Seborrheic dermatitis: apply the cream onto the infected area 1 to 2 times daily, depending on the type and extent of the infection. In that case, it is also recommended to pursue the treatment continuously until 1 week after the complete disappearance of the lesion

If you use more MICOZAL cream than you should:

If you apply too much MICOZAL cream, you could experience local burning sensation or redness or swelling. If you discontinue the treatment, burning sensation and redness disappears.

MICOZAL cream should not be swallowed. If anyone swallows accidentally MICOZAL cream contact a doctor.

If you have used too much MICOZAL cream or swallowed the cream, contact your doctor or your pharmacist or the casualty department straight away.

4. POSSIBLE SIDE EFFECTS

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

Reactions at application site such as burning sensation, itching and redness are observed frequently. Hypersensitivity reactions (allergic reactions), cutaneous eruption, rash, bullous eruption (with blistering of the skin), skin exfoliation, wet skin and reactions at application site such as bleeding, discomfort, dryness, inflammation, tingling and irritation are less frequent. You may also develop hives (also known as nettle rash or urticaria)

EXPHAR SA	May 2019	MICOZAL – Cream
	Administrative Information and Product Information	Module 1 - Page 34 of 51

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

5. HOW TO STORE MICOZAL CREAM

Keep out of the sight and reach of children.

Keep the tube tightly close.

Do not use MICOZAL CREAM after the expiry date stated on the outer pack. The expiry date refers to the last day of that month.

Store below 30 °C.

6. CONTENT OF THE PACK AND OTHER INFORMATION

What does MICOZAL CREAM contain?

The active substance is ketoconazole (2 % w/w)

The other ingredients are: sodium sulphite, propylene glycol, stearyl alcohol, cetyl alcohol, polysorbate 60, polysorbate 80, isopropyl myristate, sorbitan stearate and purified water.

What MICOZAL CREAM looks like and contents of the pack?

MICOZAL cream is a white cream available in 15 g tube.

MICOZAL CREAM® is a registered trademark of
Exphar s.a. Zoning Industriel de Nivelles Sud, Zone II - Av. Thomas Edison 105 - 1402 Thines
(Belgium)

Manufacturer

Gracure Pharmaceuticals Ltd.,
E-105 Industrial area, Phase III, Bhiwadi (Raj.) INDIA.

The last date this package leaflet was revised is 02/2018