

PATIENT INFORMATION LEAFLET

OLY[®] 1% cream **External use.**

Active ingredient: 1 g of OLY[®] contains 10 mg (1%) of isoconazole nitrate.

Excipients: Liquid paraffin, white soft paraffin, tween 60, cetostearyl alcohol, disodium EDTA, sorbitan stearate and deionized water.

Read all of this PATIENT INFORMATION LEAFLET carefully before you start taking this medicine, because it contains important information for you.

- *Keep this leaflet because you may need to read it again.*
- *If you have any further questions or are not sure about anything, please ask your doctor or your pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others as it may harm them, even if their symptoms are the same as yours.*
- *Tell your doctor or pharmacist that you use this medicine if you visit your doctor or go to the hospital.*
- *Strictly follow these instructions. Do not take **lower or higher doses** than the recommended dose.*

What is in this leaflet:

- 1. What OLY[®] is and what it is used for?**
- 2. What you need to know before you use OLY[®]**
- 3. How to use OLY[®]?**
- 4. Possible side effects**
- 5. How to store OLY[®]?**

1. What OLY[®] cream is and what it is used for?

1 g of OLY[®] contains 10 mg of isoconazole nitrate. Isoconazole nitrate belong to a group of drugs used externally to treat fungal infections of the skin, known as the imidazole group. OLY[®] is available in 30 g tubes.

OLY[®] is also effective against fungi, yeast, yeast-like fungi (including organisms causing fungal infection marked with light brown spots flaking in the upper chest skin and upper parts of the arms) and molds, also against organisms that cause the infectious skin disease (erythrasma) marked with red-brown spots with thin crusts especially on the groin, spaces between the toes, armpits and under the breasts.

2. What you need to know before you use OLY[®] Cream

Do not use OLY[®] Cream

If you are allergic to the active ingredient isoconazole nitrate or any of the other ingredients of this medicine.

Take special care with OLY[®]

If used on the face, OLY[®] should not be allowed to come into contact with the eyes.

To prevent reinfection, the patient's personal linen (flannel, towel and - preferably cotton - underwear) should be changed and boil-washed daily.

It is often advisable to place a strip of gauze smeared with OLY[®] between the toes or fingers if these areas are affected.

A regular and careful cleaning routine is vital to the success of treatment with OLY[®]. In the case of tinea pedis, the spaces between the toes must be dried thoroughly after washing and socks and stockings must be changed every day.

Taking OLY[®] with food and drinks

You can use OLY[®] while you eat and drink

Pregnancy

Ask your doctor or pharmacist for advice before taking any medicine.

Tell your doctor that you are pregnant or you may be pregnant because your doctor will want to take this into account before prescribing OLY[®].

Data on the use of isoconazole-containing products during pregnancy indicate no risk of congenital abnormalities in humans.

If you notice that you have been pregnant during treatment, consult immediately your doctor or pharmacist.

Lactation

Before using this medicine consult your doctor or pharmacist.

Effective quantities of isoconazole are unlikely to be secreted in breast milk.

Driving and using machines:

OLY[®] has no known effect on driving and use of machines.

Important information on some excipients present in OLY[®]

If you are not allergic to the excipients contained in OLY[®], an adverse reaction to these excipients is not expected.

OLY[®] contains cetyl stearyl alcohol that can cause local skin reactions (e.g. contact dermatitis).

OLY[®] contains sodium. However, it does not require any warning because of the method of use.

Taking other medicines

There are no known interactions.

If you are taking or have recently taken any other medicines, including medicines without a prescription, tell your doctor or pharmacist.

3. HOW TO USE OLY[®]

Instructions for proper use and dosage/administration frequency:

Always use OLY[®] exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Unless prescribed otherwise by your doctor, OLY[®] Cream is applied once daily to the infected areas of skin.

Duration of treatment is 2-3 weeks, 4 weeks in the case of stubborn infections (especially when the spaces between the toes are involved). Longer courses of treatment may also be prescribed.

In order to prevent recurrences, treatment should be continued for at least another 2 weeks after your symptoms have disappeared.

Route and method of administration:

OLY[®] is externally applied to the infected areas of the skin.

If you have the impression that the effect of OLY[®] is too strong or weak, talk with your doctor or pharmacist.

If you use more OLY[®] than you should

If you use more OLY[®] than was prescribed, do not worry, tell your doctor or pharmacist.

An overdose for once (one time application to a large area of the skin) or accidental indigestion is unlikely to cause any risk.

If you forget to use OLY[®]

Your doctor will decide when you will use the missed dose. It is important that you follow the instructions of your doctor for the next application.

Do not take double dose to make up the dose you have missed.

Effects that may occur if you stop taking OLY[®]

If you use OLY[®] as recommended by your doctor, symptoms will disappear during treatment and complete recovery will be achieved after treatment. If the symptoms continue or arise again, contact your doctor.

4. Possible Side Effects

Like all medicines, OLY[®] can cause side effects, although not everybody gets them.

Local symptoms such as itching, burning, erythema or vesicle formation occurred in a few isolated cases under treatment with isoconazole, the active ingredient of OLY[®] 1% cream.

Allergic skin reactions may also occur.

Tell your doctor or pharmacist if you notice any other effects not listed in this leaflet..

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is very important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to Turkish Pharmacovigilance Center (TUFAM) (www.titck.gov.tr e-mail: tufam@titck.gov.tr; tel: 0 800 314 00 08; fax: 0 312 218 35 99).

5. How To Store OLY®

Store OLY® in its original packaging and keep out of the reach and sight of children.

Store at room temperature, below 25°C.

Use in compliance with the expiry date.

Do not use OLY® after the expiry date which is stated on the packaging.

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This leaflet is approved on ____ / ____ / ____.