

## **PACKAGE LEAFLET: Information for the patient**

### **MIKONAL**

Ovules – 100 mg

(Miconazole nitrate)

**Read all of this leaflet carefully before you start using this medicine.**

- 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

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

### **1. WHAT MIKONAL IS AND WHAT IT IS USED FOR**

Mikonal contains the active substance miconazole nitrate which is an imidazole antifungal with similar activity to that of ketoconazole. *In vitro*, it also has some activity against *Cladosporium*, *Madurella*, some *Phialophora*, *Pseudallescheria boydii* and gram-positive bacteria including some staphylococci and streptococci.

A great number of fungi sensible to miconazole can be inhibited in concentrations of 2 mcg per ml or less.

Small amounts of miconazole are absorbed through the skin or mucous membranes when it is used locally, as cream, solution or vaginal ovules.

Mikonal is used in vaginal and vulvovaginal mycotic infections caused mainly by *Candida*. The symptoms of this infection include itching, redness and white vaginal discharge. Ovules destroy fungi that cause these infections and some bacteria, which are also present.

## **2. BEFORE YOU USE MIKONAL**

Do not use Mikonal if you have known hypersensitivity to miconazole nitrate or to any imidazole derivative antifungal agent and also to any of the excipients of the ovule.

Mikonal should not be used by children.

### **Take special care with Mikonal**

You should not use Mikonal ovules for self-medication if you have symptoms such as: abdominal pain, fever, or malodorous vaginal discharge, as a condition more serious than vulvovaginal candidiasis may exist.

You should consult with your doctor or pharmacist before using this drug if you are using a contraceptive method like “diaphragms”, condoms, or spermicides because vaginal ovules may damage the rubber and stop the action of this contraception. You should talk with your doctor about another method of contraception while using this drug.

During the treatment of genital areas, it is preferable that also the sexual partner has a topical treatment cycle for prevention.

You should be sure not to infect the others; do not allow the others to use your towel.

Mikonal may cause burning sensation and irritation. Cases when irritation appears indicate hypersensitivity reaction and in this case the treatment should be discontinued.

Long-term treatment may cause invasion of other bacteria not sensible to the drug. If suprainfection occurs, the treatment should be discontinued, and another appropriate treatment may be initiated.

### **Taking other medicines**

Concomitant treatment with other drugs can affect or be affected by Mikonal.

Please, tell your doctor or pharmacist if you are taking, have recently taken other medicines, including medicines obtained without a prescription. Do not forget to inform your doctor about the treatment with Mikonal if you are given another drug during treatment.

It is particularly important to inform your doctor that you are taking medicines to thin the blood (anticoagulants) such as warfarin or acenocoumarol. Mikonal, even when used locally, may enhance their action.

Caution should be exercised also when miconazole is co-administered with oral hypoglycaemic drugs, phenytoin or simvastatin.

### **Pregnancy and breastfeeding**

Consult with your doctor or pharmacist before using this drug during pregnancy or breastfeeding. During pregnancy or breastfeeding, vaginal ovules should be used only in cases where it is very necessary and under the direct control of the doctor.

## **3. HOW TO USE MIKONAL**

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

### **It should not be used in children.**

Ovules are inserted high into the vagina, best done in the reclining position.

- Use one ovule every evening for 7 or 14 days, or one ovule twice daily for 7 days if your doctor recommends so.
- Your symptoms may disappear early but you should continue using the ovules as long as your doctor has recommended you. If you stop the treatment before the recommended therapy, the symptoms may appear again.
- Use the ovules at bedtime. This will help you because you stay in one place.
- Do not swallow the ovules.
- In event of relapse, an antibiogram should be performed and the diagnosis should be

confirmed so that another treatment may be initiated again.

### **If you use more Mikonal**

If you use more Mikonal than you should or accidentally swallow the ovules, or if the children swallow it accidentally, please contact your doctor, the hospital or any medical care site to seek advice on the risk and the appropriate measures.

Anyway, even in cases of overdosage in humans, no adverse effects have been reported. Taking a higher dose than the dose recommended by your doctor is normally harmless. Anyway, you should talk with your doctor.

If swallowed: nausea, vomiting, diarrhea may occur which may need symptomatic treatment.

### **If you forget to use Mikonal**

If you forget to use one dose, use the next dose at its usual time. Do not use a double dose to make up a forgotten dose.

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

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Mikonal may cause side effects, although not everybody gets them.

Sometimes they may be serious, sometimes not. Do not worry about this list of possible side effects. None of them may appear to you.

In the beginning of the treatment vaginal burning sensation, pruritus and irritation, pelvic cramps, exanthema and headache may occur. In these cases the treatment should be discontinued and another appropriate treatment should be initiated.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## **5. HOW TO STORE MIKONAL**

Keep out from the reach and sight of children!

Do not use Mikonal after the expiry date which is stated on the package.

Do not store above 25°C!

Keep in the original package to protect it from light.

## **6. FURTHER INFORMATION**

### **What Mikonal ovules contain**

The **active substance** is miconazole nitrate.

1 ovule contains 100 mg miconazole nitrate.

The **excipient** is: hard fat.

### **Contents of the pack**

Box with 10 ovules.

### **Marketing Authorisation Holder (MAH) and Manufacturer:**

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

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