

**PACKAGE LEAFLET**

## Package leaflet: Information for the patient

**Lomexin 200 mg soft vaginal capsules**

**Lomexin 600 mg soft vaginal capsules**

Fenticonazole nitrate

[For medicines available only on prescription:]

**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.

[For medicines available without a prescription:]

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

Always take this medicine exactly as described in this leaflet or as your pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

### What is in this leaflet

1. What Lomexin is and what it is used for
2. What you need to know before you use Lomexin
3. How to use Lomexin
4. Possible side effects
5. How to store Lomexin
6. Contents of the pack and other information

#### 1. What Lomexin is and what it is used for

Lomexin contains the active substance fenticonazole nitrate. It is an antifungal agent particularly effective against *Candida*.

[For medicines available only on prescription:]

Lomexin is used to treat a common vaginal infection known as vaginal candidiasis (vaginal thrush) in adolescents more than 16 years and adults.

[For medicines available without a prescription:]

Lomexin is used to treat a common vaginal infection known as vaginal candidiasis (vaginal thrush) in adolescents more than 16 years and adults. For treatment in women over 60 years, prior consultation with a physician is required.

Lomexin vaginal capsules are for insertion in the vagina only.

#### 2. What you need to know before you use Lomexin

##### Do not use Lomexin:

- if you are allergic to fenticonazole or any of the other ingredients of this medicine (listed in section 6).

## Warnings and precautions

Talk to your doctor or pharmacist if:

- You are pregnant or breastfeeding (see section “Pregnancy, breast-feeding and fertility”).
- You are using a “barrier” method of contraception made of latex (see section “Other medicines and Lomexin”). Consequently, you should use alternative precautions while using this product.
- You experience any irritation or sensitivity to the product.
- Your symptoms are not reduced within one week or in case of severe or recurrent symptoms.
- Your partner is also affected.
- You had more than two previous infections in the last 6 months.
- You or your partner have ever had a sexually transmitted disease.
- You have ever had hypersensitivity to imidazoles or other vaginal antifungal products.
- You are aged under 16 or over 60
- You have any of the following symptoms:
  - Abnormal or irregular vaginal bleeding
  - Blood staining of a vaginal discharge
  - Vulval or vaginal sores, ulcers or blisters
  - Lower abdominal pain or dysuria
  - Adverse effects such as redness, itching or rash associated with the treatment

## Children and adolescents

Lomexin is not recommended for children under 16 years.

## Other medicines and Lomexin

The fatty excipients and oils contained in the soft vaginal capsules may damage contraceptives made of latex, such as condoms and diaphragms (see “Warnings and precautions” section).

## Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding or think you may be pregnant, ask your doctor for advice before using this medicine. Lomexin should be used in pregnancy and breastfeeding periods under the supervision of a physician.

## Driving and using machines

Lomexin has no influence on the ability to drive and use machines.

## Lomexin contains:

- sodium ethyl parahydroxybenzoate and sodium propyl parahydroxybenzoate which may cause allergic reactions (possibly delayed).

## 3. How to use Lomexin

### [For medicines available only on prescription:]

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

### [For medicines available without prescription:]

Always take this medicine exactly as described in this leaflet or as your pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Lomexin vaginal capsule is for vaginal use only. Do not swallow it.

The vaginal capsule should be inserted as deep as possible into the vagina at bedtime.

The recommended dose is:

- 1 soft vaginal capsule of 200 mg for three consecutive days;

- 1 soft vaginal capsule of 600 mg (single administration). If symptoms persist, a second dose may be administered after three days.

### **If you use more Lomexin than you should**

In case the vaginal capsule is eaten or swallowed, contact a doctor immediately or go to the nearest hospital.

### **If you forget to use Lomexin**

Do not use a double dose to make up for a missed dose.

### **If you stop using Lomexin**

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.

A slight burning sensation may be experienced when the medicine is inserted into the vagina. This will quickly disappear. When used as recommended, Lomexin is absorbed only slightly and no side effects involving the entire body (systemic effects) are reported.

The use of medicines for topical use, especially if prolonged, may cause sensitization (see “Warnings and precautions” section).

The following side effects have been reported with Lomexin:

### **Very rare (may affect up to 1 in 10,000 people):**

- vulvovaginal burning sensation
- skin erythema, pruritus and rash

### **Reporting of 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 listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Lomexin**

Do not store above 30°C.

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 carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **Lomexin 200 mg soft vaginal capsules**

- The active substance is fenticonazole nitrate. 1 soft vaginal capsule contains 200 mg of fenticonazole nitrate.
- Other ingredients: medium-chain triglycerides, silica, colloid anhydrous. The capsule shell contains gelatin, glycerol, titanium dioxide (E 171), sodium ethyl parahydroxybenzoate (E 215), sodium propyl parahydroxybenzoate (E 218).

### **Lomexin 600 mg soft vaginal capsules**

- The active substance is fenticonazole nitrate. 1 soft vaginal capsule contains 600 mg of fenticonazole nitrate.
- Other ingredients: light liquid paraffin, white soft paraffin, soy lecithin. The capsule shell contains gelatin, glycerol, titanium dioxide (E 171), sodium ethyl parahydroxybenzoate (E 215), sodium propyl parahydroxybenzoate (E 218).

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

200 mg soft vaginal capsules: blister with 3 ivory drop-shaped vaginal capsules, soft.

600 mg soft vaginal capsules: blister with 1 ivory white ovule-shaped soft vaginal capsule.

### **Marketing Authorisation Holder and Manufacturer**

#### Marketing Authorisation Holder:

Recordati Ireland Limited, Raheens East, Ringaskiddy, CO. Cork, Ireland

#### Manufacturer:

CATALENT ITALY S.p.A. via Nettunense Km 20,100 Aprilia (LT), Italy

### **This medicinal product is authorised in the Member States of the EEA under the following names:**

Belgium <{Name of the medicinal product}>

Croatia

Denmark

Estonia

Luxembourg

Netherlands

Slovenia

**This leaflet was approved in {MM/YYYY}**