

Package leaflet: Information for the patient

[Invented name], 500 mg, vaginal tablet

Clotrimazolum

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

Always take this medicine exactly as described in this leaflet or as your doctor or 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 [Invented name] is and what it is used for
2. What you need to know before you take [Invented name]
3. How to take [Invented name]
4. Possible side effects
5. How to store [Invented name]
6. Contents of the pack and other information

1. What [Invented name] is and what it is used for

The active substance of [Invented name] is clotrimazole, which belongs to a group of medicines called imidazoles. It has a wide range of antifungal activity, i.e. destroys fungi and inhibits their growth. It is effective against microorganisms, such as dermatophytes, yeasts and moulds.

[Invented name] is used to treat infections of the vagina and vulva (female external genitalia) caused by microorganisms, such as fungi (usually *Candida*), sensitive to clotrimazole.

The product is intended for use in adults and adolescents aged 16 years and more.

Vulvovaginal candidiasis (vaginal thrush) is an occasional infection in women caused by a fungus called *Candida*. This fungus occurs among others on the skin and in the vagina, and in some cases may become pathogenic.

Vaginal fungal infections appear when the natural balance in the body is disturbed by factors, such as the use of antibiotics, certain antidiabetic drugs, contraceptives, vaginal damage and general weakness of the body. It is followed by an increase of the amount of yeasts and the development of vaginal infection.

The most common symptoms of vaginal infection are:

- itching in and around the vagina;
- pain and burning sensation, worsening as a result of friction and scratching; in addition, urine may exacerbate these symptoms as a result of tissue irritation;
- vaginal discharge (white, odorless vaginal secretions), which tend to increase before menstruation.

Vaginal infections may recur. To prevent this, you must comply with several rules:

- wash and dry the vagina in a gentle way to avoid irritation;

- avoid wearing tight clothes;
- wear cotton underwear, wear stockings instead of tights;
- avoid perfumed soaps and deodorants for intimate hygiene and bathing fluids;
- often replace tampons because a tampon filled with blood is the perfect breeding ground for yeasts.

During sexual intercourse, delicate tissue may be damaged and candidiasis can be exacerbated; also the female partner may become infected (in men the infection is often asymptomatic, so the male partner may not know about their disease); also the male partner may become infected with candidiasis. In this case, the male partner should also receive antifungal treatment.

Do not use the medicine on your own if other oral antifungals have failed during treatment of the current infection.

See section 2 for information on what situations you should consult your doctor or pharmacist before taking [Invented name].

2. What you need to know before you take [Invented name]

Do not use [Invented name]:

If you are allergic (hypersensitive) to clotrimazole or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking [Invented name]:

- when the vaginal infection occurred for the first time,
- in case of a vaginal infection in the first trimester of pregnancy,
- when there have been 4 or more cases of infections in the past year,
- if you have a fever of 38°C or higher,
- if you experience pain in the lower abdomen, back pain,
- in the case of fetid vaginal discharges,
- in the case of nausea,
- in the case of vaginal bleeding and/or pain in your arms.

[Invented name] should not be used during menstruation. You should stop using this medicine before you start your period.

Do not use tampons, vaginal lavage, spermicides or other vaginal products during treatment with [Invented name].

You should avoid having sex while you are taking [Invented name], as your infection may be passed onto your sexual partner.

The sexual partner should receive simultaneous topical treatment if he has symptoms such as itching and inflammation that may indicate yeast infection. Treatment of sexual partners can help prevent reinfection.

The efficacy of latex contraceptives, such as condoms and vaginal rings, may be reduced.

[Invented name] should not be swallowed.

Children and adolescents

[Invented name] must not be used in girls under 16 years of age without consulting a doctor.

Other medicines and [Invented name]

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you are taking **tacrolimus** or **sirolimus**, medicines used to control your immune response after organ transplants.

There may be an increase in the concentration of some medicines in your blood when taken with [Invented name]. However, this is unlikely to occur with a single 500 mg dose. If you have any further questions as to the use of other medicine with [Invented name], ask your doctor.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

[Invented name] can be used during pregnancy. During the first 3 months of pregnancy, before using [Invented name], ask your doctor. In the last 4-6 weeks of pregnancy, intimate hygiene of the genital tract should be carefully maintained.

Breast-feeding

[Invented name] can be used during breast-feeding. Ask your doctor if you are unsure.

Fertility

No studies on the effect of clotrimazole on human fertility have been performed.

Driving and using machines

[Invented name] does not affect the ability to drive or use machines.

3. How to take [Invented name]

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

The recommended dose is:

Adults and adolescents aged 16 years and more:

- One vaginal tablet, deep intravaginal use, before bedtime.

The medicine is used in a single dose. The vaginal tablet should be inserted into the vagina as deep as possible.

Provide a moist environment of the vagina so that the tablet is completely dissolved. If not dissolved, some of the tablet may leak out of the vagina.

Duration of therapy

[Invented name] is used as a single dose.

If there is no significant improvement **after 7 days** from application, **consult your doctor** to confirm the cause of the infection. If the symptoms worsen, contact your doctor.

The treatment may be repeated. However, recurrent infections may indicate another condition that causes complaints. In case of repeated symptoms, ask your doctor.

Use in children and adolescents

[Invented name] must not be used in girls under 16 years of age without consulting a doctor.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Side effects have been reported with the following frequency:

Common (may affect more than 1 in 100 people):

- burning sensation in the vulva and vagina

Uncommon (may affect more than 1 in 1 000 people):

- abdominal pain
- itching in the vulva and vagina
- vulvovaginal erythema
- irritation in the application site

Rare (may affect more than 1 in 10 000 people):

- allergic reactions
- oedema
- skin rash
- vaginal bleeding

Not known (cannot be estimated from the available data):

- vaginal desquamation
- vaginal discomfort
- vaginal pain
- nausea
- urticaria
- vaginal discharge
- pain

If the patient experiences local adverse reactions or allergic reactions (including anaphylactic reaction, angioedema, low blood pressure, dyspnoea and/or syncope), therapy should be discontinued.

Local side effects may be similar to the symptoms of the disease. Therefore, it may be difficult to differentiate between the symptoms of infection and the side effects of the medicine.

Reporting side effects

If you get any side effects, talk to your <doctor> <or> <,> <pharmacist> <or nurse>. 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 [Invented name]

Keep this medicine out of the sight and reach of children.

This medicine does not require any special temperature storage conditions. Store in the original package in order to protect from moisture.

Do not use this medicine after the expiry date which is stated on the pack: 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

What [Invented name] contains

- The active substance is clotrimazole.
- Each vaginal tablet contains 500 mg of clotrimazole.
- The other excipients are: lactose monohydrate, maize starch, potato starch, adipic acid, sodium hydrogen carbonate, magnesium stearate, silica colloidal anhydrous, sodium laurilsulfate.

What [Invented name] looks like and contents of the pack

[Invented name] 500 mg is a vaginal tablet with a white, biconvex, elongated tablet, rounded on one side, straight beveled on the other.

Tablet dimensions: 24.5 mm (length) x 10.0 mm (width).

Packaging: OPA/Aluminium/PVC/Aluminium blister containing 1 vaginal tablet.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicine is authorised in the Member States of the European Economic Area under the following names:

This leaflet was last revised in: