

Package leaflet: Information for the user

Bandida 150 mg hard capsule

fluconazole

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, pharmacist or nurse 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, pharmacist or nurse. 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 {X} days.

What is in this leaflet

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

1. What Bandida is and what it is used for

Bandida is one of a group of medicines called “antifungals”. The active substance is fluconazole.

Bandida is used in adults to treat infections caused by fungi. The most common cause of fungal infections is a yeast called *Candida*.

You might be given this medicine by your doctor to treat genital thrush, infection of the vagina or penis.

2. What you need to know before you take Bandida

Do not take Bandida:

- if you are allergic to fluconazole or any of the other ingredients of this medicine (listed in section 6), or if you are allergic to other medicines you have taken to treat a fungal infection or thrush. The symptoms may include itching, reddening of the skin or difficulty in breathing
- if you are taking astemizole or terfenadine (antihistamine medicines for allergies)
- if you are taking cisapride (used for stomach upsets)
- if you are taking pimozone (used for treating mental illness)
- if you are taking quinidine (used for treating heart arrhythmia)
- if you are taking erythromycin (an antibiotic for treating infections)

Warnings and precautions

Talk to your doctor or pharmacist before taking Bandida.

This is particularly important if:

- you have liver or kidney problems

- you suffer from heart disease, including heart rhythm problems
- you have abnormal levels of potassium, calcium or magnesium in your blood
- you develop severe skin reactions (itching, reddening of the skin or difficulty in breathing).
- you develop signs of ‘adrenal insufficiency’ where the adrenal glands do not produce adequate amounts of certain steroid hormones such as cortisol (chronic, or long lasting fatigue, muscle weakness, loss of appetite, weight loss, abdominal pain)

Other medicines and Bandida

Tell your doctor or pharmacist **immediately** if you are taking astemizole, terfenadine (an antihistamine for treating allergies) or cisapride (used for stomach upsets) or pimozide (used for treating mental illness) or quinidine (used for treating heart arrhythmia) or erythromycin (an antibiotic for treating infections) as these should not be taken with Bandida (see section: “Do not take Bandida if you”).

There are some medicines that may interact with Bandida.

Make sure your doctor knows if you are taking any of the following medicines:

- rifampicin or rifabutin (antibiotics for infections)
- alfentanil or fentanyl (used as anaesthetic)
- amitriptyline or nortriptyline (used as anti-depressant)
- amphotericin B or voriconazole (anti-fungal)
- medicines that thin the blood to prevent blood clots (warfarin or similar medicines)
- benzodiazepines (midazolam, triazolam or similar medicines) used to help you sleep or for anxiety
- carbamazepine or phenytoin (used for treating fits)
- nifedipine, isradipine, amlodipine, felodipine and losartan (for hypertension - high blood pressure)
- ciclosporin, everolimus, sirolimus or tacrolimus (to prevent transplant rejection)
- cyclophosphamide or vinca alkaloids (vincristine, vinblastine or similar medicines) used for treating cancer
- halofantrine (used for treating malaria)
- statins (atorvastatin, simvastatin and fluvastatin or similar medicines) used for reducing high cholesterol levels
- methadone (used for pain)
- celecoxib, flurbiprofen, naproxen, ibuprofen, lornoxicam, meloxicam, diclofenac (Non-Steroidal Anti-Inflammatory Drugs (NSAID))
- oral contraceptives
- prednisone (steroid)
- zidovudine, also known as AZT, or saquinavir (used in HIV-infected patients)
- medicines for diabetes such as chlorpropamide, glibenclamide, glipizide or tolbutamide
- theophylline (used to control asthma)
- vitamin A (nutritional supplement)
- ivacaftor (used for treating cystic fibrosis)
- amiodarone (used for treating uneven heartbeats “arrhythmias”)
- hydrochlorothiazide (a diuretic)

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

Bandida with food and drink

You can take this medicine with or without a meal.

Pregnancy, breast-feeding and fertility

You should not take Bandida while you are pregnant or breast-feeding unless your doctor has told you to.

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.

Driving and using machines

Bandida may cause dizziness or fits. If affected, do not drive or use machines.

Bandida contains lactose

This medicine contains a small amount of lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Bandida

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

The recommended dose is:

Adults

150 mg as a single dose

Swallow the capsule whole with a glass of water.

Elderly

The usual adult dose should be given.

Patients with kidney problems

The usual adult dose should be given.

How quickly will the treatment start to work?

Vaginal thrush:

Your condition should start to clear up within a few days - some women notice an improvement in one day. If your condition does not clear up within a few days you should talk to your doctor.

Thrush infection of the penis:

Your condition should start to clear up within a few days but it may take up to a week. If your condition has not cleared up after one week, you should talk to your doctor.

If you take more Bandida than you should

Taking too many capsules at once may make you unwell. Contact your doctor or your nearest hospital casualty department at once. The symptoms of a possible overdose may include hearing, seeing, feeling and thinking things that are not real (hallucination and paranoid behaviour). Symptomatic treatment (with supportive measures and gastric lavage if necessary) may be adequate.

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 few people develop **allergic reactions** although serious allergic reactions are rare. If you get any of the following symptoms, **tell your doctor immediately:**

- sudden wheezing, difficulty in breathing or tightness in the chest
- swelling of eyelids, face or lips
- itching all over the body, reddening of the skin or itchy red spots

- skin rash
- severe skin reactions such as a rash that causes blistering (this can affect the mouth and tongue).

Bandida may affect your liver. The signs of liver problems include:

- tiredness
- loss of appetite
- vomiting
- yellowing of your skin or the whites of your eyes (jaundice)

Bandida may affect your adrenal glands and the levels of steroid hormones produced. The signs of adrenal problems include:

- tiredness
- muscle weakness
- loss of appetite
- weight loss
- abdominal pain

If any of these happen, **tell your doctor immediately.**

Other side effects:

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

Common (may affect up to 1 in 10 people):

- headache
- stomach discomfort, diarrhoea, feeling sick, vomiting
- increases in blood tests of liver function
- rash

Uncommon (may affect up to 1 in 100 people):

- reduction in red blood cells which can make skin pale and cause weakness or breathlessness
- decreased appetite
- inability to sleep, feeling drowsy
- fit, dizziness, sensation of spinning, tingling, pricking or numbness, changes in sense of taste
- constipation, difficult digestion, wind, dry mouth
- muscle pain
- liver damage and yellowing of the skin and eyes (jaundice)
- wheals, blistering (hives), itching, increased sweating
- tiredness, general feeling of being unwell, fever

Rare (may affect up to 1 in 1,000 people):

- lower than normal white blood cells that help defend against infections and blood cells that help to stop bleeding
- red or purple discoloration of the skin which may be caused by low platelet count, other blood cell changes
- low blood potassium
- blood chemistry changes (high blood levels of cholesterol, fats)
- shaking
- abnormal electrocardiogram (ECG), change in heart rate or rhythm
- liver failure
- allergic reactions (sometimes severe), including widespread blistering rash and skin peeling, severe skin reactions, swelling of the lips or face
- hair loss

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Bandida

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

Do not store above 30°C.

Store in the original package to protect from moisture.

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 Bandida contains

- The active substance is fluconazole. Each hard capsule contains 150 mg fluconazole.
- The other ingredients are:
Capsule contents: Lactose monohydrate, pregelatinised maize starch, colloidal anhydrous silica, magnesium stearate.
Capsule shell: Gelatin, titanium dioxide (E171).

What Bandida looks like and contents of the pack

- White cap and white body, size 1 hard gelatine capsule, filled with white powder.
- Bandida comes in a blister pack containing one capsule.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Actavis Group PTC ehf.
Reykjavíkurvegi 76-78
220 Hafnarfjörður
Iceland

Manufacturer:

Actavis ehf.
Reykjavíkurvegi 78
220 Hafnarfjörður
Iceland

Specifar SA
1, 28 Octorviou str.
Agia Varvara, 12351
Athens, Greece

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

BG: Fungolon Stop
DK: Solona
EE: Locaring
EL: Solona
HU: Locaring
IE: Bandida
LT: Locaring
LV: Locaring
NO: Solona
PL: Locaring
RO: Fungolon Uno 150mg capsule
UK: Fluconazole 150mg Hard Capsule

This leaflet was last revised in November 2016