

## Bell's Healthcare Bell's Healthcare Thrush Relief Oral 150 mg Capsule (Fluconazole)

### PACKAGE LEAFLET: INFORMATION FOR THE USER

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 7 days.

#### What is in this leaflet

1. What Bell's Healthcare Thrush Relief Oral 150 mg Capsule is and what it is used for
2. What you need to know before you take Bell's Healthcare Thrush Relief Oral 150 mg Capsule
3. How to take Bell's Healthcare Thrush Relief Oral 150 mg Capsule
4. Possible side effects
5. How to store Bell's Healthcare Thrush Relief Oral 150 mg Capsule
6. Contents of the pack and other information

#### 1. What Bell's Healthcare Thrush Relief Oral 150 mg Capsule is and what it is used for

Bell's Healthcare Thrush Relief Oral 150 mg Capsule is a full course of treatment for thrush.

**Only use this product if you have been previously diagnosed by your doctor as having thrush.**

The active substance is Fluconazole. It belongs to a group of medicines called azoles and is an antifungal agent. It fights the cause of infections such as thrush.

#### 2. What you need to know before you take Bell's Healthcare Thrush Relief Oral 150 mg Capsule

**Do not take Bell's Healthcare Thrush Relief Oral 150 mg Capsule if you:**

- are allergic to Fluconazole, to other medicines you have taken to treat fungal infections or to any of the other ingredients of this medicine (listed in section 6).
- are taking astemizole, terfenadine (antihistamine medicines for allergies)
- are taking cisapride (used for stomach upsets)
- are taking pimozide (used for treating mental illness)
- are taking quinidine (used for treating heart arrhythmia)
- are taking erythromycin (an antibiotic for treating infections)
- suffer from porphyria.

#### Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Fluconazole if you:

- are unsure about the cause of your symptoms
- have had thrush more than twice in the last six months
- or your partner have ever been exposed to a sexually transmitted disease
- are taking any medicine other than the contraceptive pill
- suffer from any chronic disease or illness
- are aged under 16 or over 60 years
- have liver or kidney problems
- suffer from heart disease, including heart rhythm problems
- develop severe skin reactions (itching, reddening of the skin or difficulty in breathing)
- 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)
- if the fungal infection does not improve, an alternative antifungal therapy may be needed
- have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Bell's Healthcare Thrush Relief Oral 150 mg Capsule.

Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with Bell's Healthcare Thrush Relief Oral 150 mg Capsule treatment. Stop taking Bell's Healthcare Thrush Relief Oral 150 mg Capsule and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

#### Women only:

- if you are pregnant, suspect you might be pregnant or are breast-feeding
- if you have any abnormal or irregular vaginal bleeding or a blood stained discharge
- if you have vulval or vaginal sores, ulcers or blisters
- if you are experiencing lower abdominal pain or burning on passing urine.

#### Men only:

- if your sexual partner does not have vaginal thrush
- if you have penile sores, ulcers or blisters
- if you have an abnormal penile discharge (leakage)
- if your penis has started to smell
- if you have pain on passing urine.

#### Children (under 16 years):

Paediatric use is not recommended.

#### Other medicines and Bell's Healthcare Thrush Relief Oral 150 mg Capsule:

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

There are some medicines that may interact with Fluconazole. Make sure your doctor knows if you are taking any of the following medicines:

- rifampicin or rifabutin (antibiotics for infections)
- alfentanil, fentanyl (used as anaesthetic)
- amitriptyline, nortriptyline (used as anti-depressant)
- amphotericin B, 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)
- olaparib (used for treating ovarian cancer)
- nifedipine, isradipine, amlodipine, verapamil, felodipine and losartan (for hypertension - high blood pressure)
- ciclosporin, everolimus, sirolimus or tacrolimus (to prevent transplant rejection)
- cyclophosphamide and 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 (used to treat allergies)
- zidovudine, also known as AZT; 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)
- ibrutinib (used for treating blood cancer)
- tofacitinib (used for treating rheumatoid arthritis)
- lurasidone (used for treating schizophrenia and bipolar disorder)
- abrocitinib (used for treating atopic dermatitis)
- tolvaptan used to treat hyponatremia (low levels of sodium in your blood) or to slow kidney function decline.

#### Pregnancy, breast-feeding and fertility

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. You should not take Bell's Healthcare Thrush Relief Oral 150 mg Capsule if you are pregnant, think you may be pregnant or are trying to become pregnant or breast-feeding, unless your doctor has told you so.

Fluconazole taken during the first trimester of pregnancy may increase the risk of miscarriage. Fluconazole taken at low doses during the first trimester may slightly increase the risk of a baby being born with birth defects affecting the bones and/or muscles.

#### Driving and using machines

Bell's Healthcare Thrush Relief Oral 150 mg Capsule may occasionally cause dizziness or fits. If affected do not drive or use machinery.

#### Bell's Healthcare Thrush Relief Oral 150 mg Capsule contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

#### Information on sodium content

Bell's Healthcare Thrush Relief Oral 150 mg Capsule contain less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

#### 3. How to take Bell's Healthcare Thrush Relief Oral 150 mg Capsule

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.

You should read the instructions on the pack. Bell's Healthcare Thrush Relief Oral 150 mg Capsule should only be taken by mouth.

The whole course of treatment for vaginal thrush is one capsule which you take by mouth. Take the capsule with a glass of water.

Some women notice an improvement after one day and the thrush should clear up after 2 days. If symptoms persist for more than 7 days, consult your doctor.

If after treatment with Bell's Healthcare Thrush Relief Oral 150 mg Capsule you have a reoccurrence of thrush, you should only take this product again if it has been more than 7 days since your last treatment.

If you experience a thrush infection more than twice over a six month period, consult your doctor.

Remember that Fluconazole can only treat thrush. It cannot treat other infections of the genitals. If you still have any sort of symptoms one or two days after you have taken Fluconazole, you should visit your doctor in case you have another type of infection.

**If you take more Bell's Healthcare Thrush Relief Oral 150 mg Capsule than you should**  
If you (or someone else) swallow a lot of capsules at the same time, or you think a child has swallowed any of the capsules, contact your doctor, pharmacist or hospital emergency department immediately.

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. These can be seen even with a single dose of 150 mg.

**STOP taking Bell's Healthcare Thrush Relief Oral 150 mg Capsule straight away and contact your doctor immediately if you experience:**

- a serious allergic reaction (anaphylaxis) or hypersensitivity including an itchy rash (hives), itching, sore mouth or eyes, fever, swelling of the face, lips, throat or tongue
- a sudden wheeziness or tightness of the chest
- liver problems such as yellowing of the skin or whites of the eyes (jaundice), dark coloured urine, or changes in the way your liver works (that may show up in blood tests)
- a severe skin rash with flushing, fever, blisters or ulcers (Stevens-Johnson syndrome)
- a severe rash with reddening, peeling and swelling of the skin that looks like a burn (toxic epidermal necrolysis)
- hypersensitivity reaction with skin rash, fever, swollen glands, increase in a type of white blood cell (eosinophilia) and inflammation of internal organs (liver, lungs, heart, kidneys and large intestine)
- Widespread rash, high body temperature and enlarged lymph node (DRESS syndrome or drug hypersensitivity syndrome).

#### 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
- increase in blood tests of liver function
- rash.

Uncommon: may affect up to 1 in 100 people

- anaemia, reduction in red blood cells which can make skin pale and cause weakness or breathlessness
- decreased appetite
- inability to sleep, feeling drowsy
- fits, dizziness, sensation of spinning, tingling, prickling or numbness, changes in sense of taste
- constipation, difficulty in digestion, wind, dry mouth
- muscle pain
- low blood potassium, which may cause muscle cramps or weakness, nausea and changes in heart rhythm
- 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 (you may have more infections than usual such as sore throats, fever or flu-like symptoms)
- lower than normal blood cells that help to stop bleeding (you may have unexplained bruising or bleeding)
- red or purple discoloration of the skin which may be caused by low platelet count, other blood cell changes
- blood chemistry changes (high blood levels of cholesterol, fats)
- shaking
- abnormal electrocardiogram (ECG), change in heart rate or rhythm
- hair loss.

Not known: frequency cannot be estimated from the available data

- hypersensitivity reaction with skin rash, fever, swollen glands, increase in a type of white blood cell (eosinophilia) and inflammation of internal organs (liver, lungs, heart, kidneys and large intestine) (Drug Reaction or rash with Eosinophilia and Systemic Symptoms (DRESS)).

#### 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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store Bell's Healthcare Thrush Relief Oral 150 mg Capsule

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

The product does not require any special storage conditions within Europe.

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 Bell's Healthcare Thrush Relief Oral 150 mg Capsule contains

- The active substance is Fluconazole. Each capsule contains 150 mg of Fluconazole.
- The other ingredients are lactose monohydrate, maize starch, sodium lauryl sulphate, colloidal silicon dioxide and magnesium stearate. The capsule shell is gelatin and the colouring agents are titanium dioxide (E171) and Patent Blue V (E131).

##### What Bell's Healthcare Thrush Relief Oral 150 mg Capsule looks like and the contents of the pack

Each capsule has a blue body and cap. Bell's Healthcare Thrush Relief Oral 150 mg Capsule come in a pack containing one capsule.

##### Further information about thrush

Vaginal thrush (candidiasis) is a common infection that most women suffer from at some stage in their lives and is not caused by lack of personal hygiene.

Thrush is caused by a yeast (fungus) called Candida, which lives harmlessly in the vagina and other parts of the body without ever being noticed. However, the natural balance that keeps Candida under control can be upset by many factors such as hormonal changes (menstruation, contraceptive pill, pregnancy, menopause), poor health, antibiotics, perfumed soaps, bath additives and tight clothing.

If the natural pH balance is altered, the level of yeast increases and can develop into a thrush infection causing any of the following symptoms: persistent burning and/or itching around the vagina and vulva, redness, swelling and soreness of the tissues of the vagina and the vulva and a whitish, odourless discharge from the vagina.

Not everybody who has thrush has all these symptoms; you may have only one of them.

In men, Candida can also cause thrush - a condition called balanitis (inflammation of the end of the penis).

It causes any of the following symptoms: soreness and redness of the penis, tightness of the foreskin and a white, odourless discharge from the penis.

##### How to avoid future recurrences

- Wear cotton underwear and avoid tight clothing
- Wash daily
- After going to the toilet, wipe yourself from front to back as a thrush infection may be transferred from the bowel
- Change your sanitary protection regularly
- Try to avoid washing with perfumed soaps and using vaginal deodorants
- Do not wash or rub yourself hard with sponges or flannels

If you are still worried or have any questions about the symptoms or the treatment of thrush, contact your doctor or pharmacist for advice.

##### Marketing Authorisation Holder and Manufacturer

Relonchem Limited, Cheshire House, Gorsey Lane, Widnes, Cheshire, WA8 0RP, UK.

**Distributor:** Bell, Sons & Co. (Druggists) Ltd., Southport, PR9 9AL, UK.

Product Licence Number: PL 20395/0042

**P**

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

D27-0476

PON/DRUGS/08 13 2289