

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### CanOral

150mg Capsule  
Fluconazole

**Read all of this leaflet carefully before you start taking 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. Do not pass it on to others. It may harm them, even if their symptoms 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.

#### **What is in this leaflet:**

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

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

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

You must take to a doctor if you do not feel better or if you feel worse after 7 days, an alternative antifungal therapy may be needed.

### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CANORAL**

#### **Do not take CanOral if you**

- are allergic to fluconazole or to any of the other ingredients of CanOral (listed in section 6). The symptoms may include itching, reddening of the skin or difficulty in breathing
- 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)

#### **Warnings and precautions**

##### **Talk to your doctor before taking CanOral if you**

- have liver or kidney problems
- suffer from heart disease, including heart rhythm problems
- have abnormal levels of potassium, calcium or magnesium in your blood
- develop severe skin reactions (itching, reddening of the skin or difficulty in breathing)

- have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using CanOral
- 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, as alternative antifungal therapy may be needed.

Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with CanOral treatment. Stop using CanOral and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

### **Children**

Although this medicine is for adults it can be used in adolescents (from 12 to 17 years old) if treatment is essential and no suitable alternative exists and should be taken in the same way as for adults.

### **Other medicines and CanOral**

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

Tell your doctor **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 CanOral (see section: “Do not take CanOral if you”).

There are some medicines that may interact with CanOral.

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, phenytoin (used for treating fits)
- verapamil, nifedipine, isradipine, amlodipine felodipine and losartan (for hypertension-high blood pressure)
- olaparib (used for treating ovarian cancer)
- ciclosporin, everolimus, sirolimus or tacrolimus (to prevent transplant rejection)
- cyclophosphamide, 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; saquinavir (used in HIV-infected patients)
- medicines for diabetes such as chlorpropamide, glibenclamide, glipizide or tolbutamide
- theophylline (used to control asthma)

- tofacitinib (used for treating rheumatoid arthritis)
- vitamin A (nutritional supplement)
- ivacaftor (used for treating cystic fibrosis)
- amiodarone (used for treating uneven heartbeats ‘arrhythmias’)
- hydrochlorothiazide (a diuretic)

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

### **CanOral with food and drink**

You can take your medicine with or without a meal.

### **Pregnancy and breast-feeding**

Tell your doctor if you are pregnant, trying to become pregnant or breast-feeding.

You should not take CanOral if you are pregnant, think you may be pregnant, are trying to become pregnant or breast-feeding, unless your doctor has told you to.

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.

You can continue breast-feeding after taking a single dose of 150 mg CanOral.

You should not breast-feed if you are taking a repeated dose of CanOral.

Ask your doctor or pharmacist for advice before taking any medicines.

### **Driving and using machines**

When driving vehicles or using machines, it should be taken into account that occasionally dizziness or fits may occur.

### **CanOral contains lactose monohydrate**

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 CANORAL**

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

Swallow the capsule whole with a glass of water.

### **Adults**

150 mg as a single dose.

Doctors sometimes prescribe different doses to these. Always take your medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

### **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 go back to your doctor.

### **Penis thrush infection**

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 go back to your doctor.

### **If you take more CanOral 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 forget to take CanOral**

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take the dose that you missed.

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

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, CanOral can cause side effects, although not everybody gets them.

Stop using CanOral and seek medical attention immediately if you notice any of the following symptoms:

- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

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).

CanOral 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)

If any of these happen, stop taking CanOral and **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 side effects which affect 1 to 10 users in 100 are listed below:

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

Uncommon side effects which affect 1 to 10 users in 1,000 are listed below:

- 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 side effects which affect 1 to 10 users in 10,000 are listed below:

- 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

Frequency not known, but may occur (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 HPRAs Pharmacovigilance Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. HOW TO STORE CANORAL**

Keep out of the sight and reach of children.

Do not use CanOral after the expiry date which is stated on the pack after EXP. The expiry date refers to the last day of the month.

Store below 30°C.

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

## **6. CONTENTS AND OTHER INFORMATION**

### **What CanOral contains**

The active substance is fluconazole.

Each hard capsule contains fluconazole 150 mg.

The other ingredients are:

#### **Capsule content:**

colloidal anhydrous silica, lactose monohydrate, magnesium stearate, maize starch and sodium lauryl sulfate.

**Capsule shell composition:** brilliant blue FCF (E133), titanium dioxide (E171) and gelatin.

**Printing ink:** black iron oxide (E172) and shellac.

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

- CanOral 150 mg hard capsules are opaque light blue capsules. They have CAN150 printed on them.
- CanOral comes in a blister pack containing one capsule.

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

#### **Product Authorisation Holder:**

Bayer Ltd, The Atrium, Blackthorn Road, Sandyford, Dublin 18, Ireland.

#### **Manufactured for Bayer Ltd by:**

TEVA UK Limited, Brampton Road, Eastbourne, BN22 9AG, United Kingdom.

**This leaflet was last approved in May 2021.**