

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Itraconazole 10mg/ml Oral Solution

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Itraconazole Oral Solution is and what it is used for

Itraconazole 10mg/ml Oral Solution (called Itraconazole Oral Solution throughout the rest of this leaflet) belongs to a group of antifungal medicines called triazole derivatives. Your medicine works by stopping growth of the fungus.

This medicine is used:

- to treat fungal infections which may occur in your mouth, throat or gullet, in patients who have HIV or a poorly functioning immune system.
- to stop you from getting fungal infections, if your immune system is not working properly due to a reduced level of white blood cells (neutropenia), as a result of a blood disorder or a bone marrow transplant.

2. What you need to know before you take Itraconazole Oral Solution

Do not take Itraconazole Oral Solution

- If you are allergic to itraconazole, or any of the other ingredients of this medicine (listed in section 6).
- If you are pregnant, thinking of becoming pregnant or breastfeeding.
- If you are taking any of the following medicines:
 - **astemizole, mizolastine or terfenadine** (antihistamines for allergies);

- **bepriidil, ivabradine or ranolazine** (which can be used to treat angina);
- **cisapride** (which can be used to treat heartburn and reduce the amount of acid in the stomach);
- **domperidone** (for nausea and vomiting)
- **dronedarone, dofetilide or quinidine** (which can be used to treat an irregular heartbeat);
- **levacetylmethadol (levomethadyl)** (which can be used to treat opioid drug addiction);
- **pimozide and sertindole** (which can be used to treat certain mental and emotional conditions);
- **atorvastatin, lovastatin and simvastatin** (medicines used to lower cholesterol);
- **triazolam** or oral **midazolam** (medicines to help you sleep);
- **dihydroergotamine** and **ergotamine** (used to help relieve the symptoms of migraine);
- **ergometrine (ergonovine)** and **methylergometrine (methylergonovine)** (used during labour or to help control bleeding after childbirth);
- **eletriptan** (used to treat migraines);
- **nisoldipine, lercanidipine or eplerenone** (used to treat high blood pressure).
- **colchicine** (for gout) when used in patients with kidney or liver problems
- **irinotecan** (for cancer)
- **dabigatran** (for blood thinning)
- **quetiapine** (for psychosis)
- **aliskiren** (for hypertension)
- **fesoterodine** (for irritated urinary bladder) when used in patients with certain kidney or liver problems
- **sildenafil** (for pulmonary arterial hypertension)
- **solifenacin** (for irritated urinary bladder) when used in patients with certain kidney or liver problems
- **ildenafil** (for erectile dysfunction) when used in men older than 75 years of age

Also, upon completing your course of Itraconazole oral solution, do not take any of the medicines listed above for 2 weeks.

Warnings and precautions

Stop taking Itraconazole Oral Solution and see your doctor immediately, or go to your nearest hospital accident and emergency department, if you experience any of the following symptoms which could be signs that your liver is not working properly:

- severe lack of appetite
- feeling or being sick
- extreme tiredness
- stomach pain

- unusually dark urine and/or pale stools

Tell your doctor immediately if you experience any of the following symptoms whilst taking Itraconazole Oral Solution:

- loss of hearing or hearing disturbances, in very rare cases patients taking Itraconazole Oral Solution have reported temporary or permanent hearing loss
- tingling, numbness or pain in your hands and feet.

Talk to your doctor, pharmacist or nurse before taking Itraconazole Oral Solution, if you have:

- if you are allergic to any other antifungal medicines such as fluconazole or ketoconazole;
- If you suffer from heart problems, including heart failure (also known as congestive heart failure or CHF), Itraconazole could make it worse. If your doctor has prescribed Itraconazole Oral Solution for you, then you should be informed, by your doctor or pharmacist, to look out for the following signs or symptoms whilst you are taking your medicine. If you experience any of the following symptoms, whilst taking your medicine, then stop taking Itraconazole Oral Solution and inform your doctor immediately, or go to your nearest hospital accident and emergency department straight away:
 - shortness of breath
 - fluid and water retention resulting in swollen ankles, legs and stomach
 - unexpected weight gain
 - dizziness, extreme tiredness or weakness
- if you have, or have had, problems with your liver such as jaundice (yellowing of the skin, or whites of the eyes), your dose of Itraconazole may have to be changed. Your doctor should give you instructions on symptoms to watch out for. If you have to take Itraconazole continuously for more than one month, your doctor may want to check your liver by doing blood tests. In addition, there may be specific medication you may not be able to take.
- if you have, or have had, problems with your kidneys, your dose of Itraconazole may have to be changed. In addition, there may be specific medication you may not be able to take.;
- if you suffer from diarrhea after taking your medicine, as your doctor may ask you to stop taking your medicine;
- if you have a very low white blood count and are at risk of developing fungal infections;

Children and the elderly

Itraconazole Oral Solution is not normally given to children and the elderly. If the doctor has prescribed this medicine for a child, or for someone who is elderly, it is because it is in their best interests. If you, as the patient or carer, are worried about the effects of taking this medicine, go back and discuss it with your doctor.

Other medicines and Itraconazole Oral Solution

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

There are some medicines that **you should not take** whilst taking Itraconazole. These are listed above under the heading “**Do not take Itraconazole Oral Solution:**” Tell your doctor or pharmacist if you are taking any medicines listed under section 2.

Tell your doctor if you have taken any of the following medicines within the last **two weeks**, the following medicines as they may stop Itraconazole Oral Solution from working properly:

- **rifampicin, rifabutin or isoniazid** (medicines used to treat tuberculosis);
- **phenobarbital, phenytoin or carbamazepine** (drugs used to treat epilepsy);
- **St Johns Wort** (a herbal remedy for depression).
- **efavirenz or nevirapine** (medicines used for HIV/AIDS)

Do not use Itraconazole oral solution within 2 weeks of taking these medicines

Before you take Itraconazole Oral Solution

Please also tell your doctor or pharmacist, if you are taking any of the medicines listed below as your doctor may need to change the dose of these medicines, or monitor you or your blood carefully. You may also suffer increased side effects:

- medicines for cancer (namely **dasatinib, lapatinib, nilotinib, or trabectedin**)
- **everolimus or temsirolimus** (given after an organ transplant)
- **rivaroxaban** (for blood clots)
- **salmeterol** (for breathing problems)
- **tamsulosin** (for male urinary incontinence)
- **ciclesonide** (for inflammation, asthma and allergies)
- **tolterodine** (for irritated urinary bladder)
- **felodipine** (for the heart or blood vessels)
- **calcium channel blockers** such as **verapamil** or **dihydropyridines** (used to treat high blood pressure or abnormal heart rhythms);
- **medicines known to affect the clotting of your blood** such as warfarin;
- **maraviroc, ritonavir- boosted darunavir, ritonavir-boosted fosamprenavir, indinavir and saquinavir** (for HIV infections);
- **certain drugs used in cancer therapy** such as bortezomib, busulfan, docetaxel, erlotinib, gefitinib, imatinib, ixabepilone, trimetrexate and **vinca alkaloids** e.g. vinblastine;
- **ciprofloxacin, clarithromycin and erythromycin** (antibiotics);
- **cyclosporine, tacrolimus, rapamycin**, also known as **sirolimus** (often given after organ transplant);
- **glucocorticoids** e.g. budesonide, dexamethasone, fluticasone and methylprednisolone (used to treat inflammation, asthma and allergies);
- **digoxin, nadolol** (medicines that act on the heart or blood vessels);
- **cilostazol** (for leg pain that occurs when walking due to poor circulation);
- **disopyramide** (to treat irregular heartbeat);

- **buspirone, alprazolam, brotizolam, perospirone and midazolam** when given by injection into a vein (to treat anxiety or to help you sleep);
- **alfentanil, buprenorphine or oxycodone and fentanyl** (used to help relieve pain);
- **methadone for treatment of drug abuse** (opioid-dependency)
- **rifabutin** (for tuberculosis);
- **ebastine** (for allergies);
- **repaglinide and saxagliptin** (used to treat diabetes);
- **aripiprazole, haloperidol or risperidone** (for psychosis)
- **aprepitant** (for nausea and vomiting)
- **sildenafil or tadalafil** (for erectile dysfunction)
- **praziquantel** (for fluke and tapeworms)
- **meloxicam** (for joint inflammation and pain)
- **cinacalcet** (for an over active parathyroid)
- **tolvaptan** (for low blood sodium levels)
- **alitretinoin** (oral) (for eczema)
- **halofantrine** (for malaria);
- **reboxetine** (used in the treatment of depression);
- **loperamide** (used to treat diarrhoea).

Itraconazole Oral Solution with food and drink

Do not take Itraconazole Oral Solution with food or drink as it reduces your body's ability to absorb the medicine. Always wait at least one hour, after taking your medicine, before you have anything to eat or drink.

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

Pregnancy

Do not take Itraconazole Oral solution if you are pregnant, unless your doctor has told you to. If you are a woman of childbearing age and could become pregnant, you should talk to your doctor about the use of appropriate contraception whilst using this medicine. If you stop taking Itraconazole Oral Solution, you must continue to use appropriate contraception until your next period after you have stopped taking the medicine.

If you do find that you are pregnant after starting a course of Itraconazole, stop taking it and tell your doctor straight away.

Breast-feeding

If you are breast-feeding do not take Itraconazole, as small amounts of the medicine could be present in your breast milk.

Driving and using machines

This medicine may make you feel dizzy, or you may find that you have blurred/double vision, or that your hearing is affected. **Do not** drive or use machines if you feel dizzy, or if your eyesight or hearing are affected.

Itraconazole Oral Solution contains:

- **Sorbitol (E420)** – if you have been told by a doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- **Sodium saccharin** and **sodium hydroxide** – this medicinal product contains 0.07mmol (or 1.56mg) sodium (salt) per 1ml of solution. To be taken into consideration by patients on a controlled sodium (salt) diet.
- **Ethanol** – the flavouring in this medicinal product contains very small amounts of ethanol (alcohol), less than 1mg per 1ml of oral solution.

3. How to take Itraconazole Oral Solution

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

The recommended dose is:

Adults - Treatment of fungal infections in your mouth, throat or gullet

- The usual dose is 20ml (200mg itraconazole) per day. The doctor may tell you to take the dose all at once, or take 10ml (100mg itraconazole) in the morning and 10ml (100mg itraconazole) in the afternoon.

If the infection has not cleared within 7 days (1 week) of starting treatment, your doctor may tell you to continue taking your medicine for a further 7 days. If your symptoms persist, speak to your doctor or pharmacist.

Adults - Treatment of fungal infections in your mouth, throat or gullet, which have already been treated with another anti-fungal medicine, but which have not cleared

- The usual dose is 10 to 20ml (100 to 200mg itraconazole) twice a day, for 14 days (two weeks).

If the infection has not cleared within 14 days (two weeks) of starting treatment, your doctor may tell you to continue taking your medicine for a further two weeks.

If your doctor has told you to take 20ml (200mg itraconazole), twice a day for 14 days (two weeks) and your infection has not improved after 14 days, speak to your doctor for advice.

Adults - Prevention of fungal infections

- The dose will be calculated depending on your body weight (usually 5mg per kg), given in two divided doses.
- Your doctor will tell you how much medicine you need to take.

Children and the elderly

- Itraconazole Oral Solution is not normally given to children and the elderly. Your doctor may prescribe it in special cases

Patients with liver or kidney problems

- If you suffer from problems with your kidneys or liver, your doctor will monitor you carefully if you are taking Itraconazole Oral Solution.
- The doctor may change the dose, of your medicine, according to your condition.
- Your doctor may give you regular blood tests while you are taking this medicine.

Route of administration:

Always wait at least one hour, after taking your medicine, before you have anything to eat or drink.

A 30ml measuring cup is provided with your medicine.

- Using the measuring cup provided, pour out the required amount of the liquid.
- The liquid should be swished around the mouth for approximately 20 seconds and then swallowed. **Do not** rinse your mouth after swallowing your medicine.
- Wash the measuring cup after use and keep it safe for the next dose.

If you take more Itraconazole Oral Solution than you should

If you or someone else takes more Itraconazole Oral Solution than has been prescribed, or you think a child has swallowed any Itraconazole Oral Solution, contact your doctor, pharmacist or hospital emergency department immediately and take your Itraconazole Oral Solution with you.

If you forget to take Itraconazole Oral Solution

- If you forget to take a dose, do not worry. Take the next dose when it is due.
- Do not take double dose to make up for a forgotten dose.

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

4. Possible side effects

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

If you have any of the following side effects while taking your medicine, stop taking this medicine and tell your doctor immediately or go to a hospital straight away.

- **Severe allergic reaction** which may include any sudden wheeziness, a red and itchy skin rash (especially affecting the whole body), difficulty in breathing, swelling of the face, mouth, lips or eyelids, unexplained high temperature (fever) and feeling faint. **If the swelling affects your throat and makes breathing and swallowing difficult, go to hospital straight away.**

- Severe skin disorder (widespread rashes with peeling skin and blisters, which may also affect the lining of your mouth, eyes or genitals).
- Severe lack of appetite, feeling or being sick, extreme tiredness, stomach pain or unusually dark urine. These symptoms could be signs that your liver is not working properly.
- Shortness of breath, swelling of ankles, legs and stomach, unexpected weight gain, dizziness, repeated waking at night, unusual fatigue (tiredness) or weakness. These symptoms could be signs of heart failure (also known as congestive heart failure).

You should also let your doctor know if you experience any of the following side effects:

- loss of hearing or hearing disturbances
- blurred or double vision
- ringing in your ears
- inability to control passing water or increased need to pass water
- tingling, numbness or pain in your hands and/or feet
- sensitivity to light
- severe upper stomach pain, often with nausea and vomiting due to inflammation of the pancreas (pancreatitis)
- diarrhoea

Other side effects

Common (may affect up to 1 in 10 people)

- Headache, Dizziness, Changes in taste
- Shortness of breath, Cough
- Stomach pain, diarrhoea, feeling sick (nausea), being sick (vomiting), upset stomach or indigestion
- Increase in the blood of substances produced by the liver (called liver enzymes)
- Rash
- High temperature (fever)

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

- Blood disorders which may mean that you get infections (possible symptom of low levels of white blood cells) more easily than normal, you bleed or bruise more easily (possible symptoms of low levels of platelets), or you start to suffer from tiredness, weakness or fatigue.
- You may have low levels of potassium in your blood (hypokalaemia), which may make your muscles feel weak and you may suffer from extreme tiredness.
- Muscle pain, painful joints
- Constipation
- Swelling or fluid retention
- Problems with your periods
- decreased feeling or sensitivity, especially in the skin
- Itching, hives

The following side effects have been reported in patients taking Itraconazole Oral Solution with unknown frequency:

- Serum sickness, which may include symptoms such as swollen lymph nodes, fever, general feeling of being unwell
- High levels of triglycerides (fats) in the blood
- increase in blood creatine phosphokinase levels
- Pins and needles or a decreased sensitivity to touch
- Difficulty breathing, shortness of breath which can be symptoms of pulmonary oedema
- Abdominal pain, fever, nausea and vomiting, which can be symptoms of pancreatitis
- Skin disorders which may result in hair loss, itching skin lesions, itching reddening and scaling of the skin
- Difficulty in getting, or maintaining, an erection (impotence)
- Temporary or permanent hearing loss
- Liver failure
- Yellowing of the skin and whites of the eyes (jaundice) which could mean that your liver is not working properly (hepatitis).

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 Section, 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 Itraconazole Oral Solution

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

Do not use after the expiry date stated on the carton or bottle label. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in original package in order to protect from light.

Once opened, use within 1 month.

Do not use this medicine if you notice any visible signs of damage to the bottle, or deterioration in your medicine. Return it to your pharmacist.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines that have passed their expiry date or that you no longer require. These measures will help to protect the environment.

6. Contents of the pack and other information

What Itraconazole Oral Solution contains

- The active substance is itraconazole. Each 1ml contains 10mg itraconazole.
- The other ingredients are hydroxypropylbetadex, sorbitol (E420), propylene glycol, cherry flavour (containing propylene glycol (E1520), caramel flavour (containing propylene glycol (E1520) and ethanol), sodium saccharin, hydrochloric acid, concentrated and sodium hydroxide (for pH adjustment) and purified water (see section 2).

What Itraconazole Oral Solution looks like and contents of the pack

Itraconazole Oral Solution is a clear, yellow solution. It is available in an amber glass bottle containing 150ml medicine. The pack also contains a 30ml plastic measuring cup.

Marketing Authorisation Holder

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Other sources of information

For any information about this medicinal product, please contact the Marketing Authorisation Holder, details provided above.

For information in large print, audio CD or Braille please telephone 00 44 (0)1283 495 280 or email medinfo@focuspharma.co.uk.