

**PACKAGE LEAFLET: INFORMATION FOR THE USER**  
**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 or pharmacist.
- 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 or pharmacist. 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 is one of a group of medicines called "antifungals". These medicines are used to treat and stop you from getting infections caused by fungi including yeasts.

You may be given this medicine:

- To treat yeast infections of the mouth, throat or food pipe (oesophagus) if you have a poor immune system
- To stop you from getting certain fungal infections if you have blood cancer or have had a bone marrow transplant and have a poor immune system.

**2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ITRACONAZOLE ORAL SOLUTION**

**DO NOT TAKE Itraconazole Oral Solution if you:**

- are **allergic** (hypersensitive) to itraconazole or any of the other ingredients (listed in section 6)
- have, or have a history of, congestive heart failure, unless you have a very serious fungal infection (see under 'Take special care')
- are pregnant, think you might be pregnant or could become pregnant (see the section on Pregnancy)
- are taking any of the following medicines:
  - terfenadine, astemizole or mizolastine (antihistamine for allergies)
  - bepridil, ivabradine or ranolazine used to treat angina (crushing chest pain)
  - nisoldipine, lercanidipine or eplerenone (used for high blood pressure)
  - cisapride (used for stomach upsets)
  - domperidone (for nausea and vomiting)
  - midazolam by mouth or triazolam (used to help you sleep or for anxiety)
  - lovastatin or simvastatin (used to lower cholesterol)
  - lurasidone, pimozide or sertindole (for conditions affecting thoughts, feelings and/or behaviour)
  - levacetylmethadol (used for treatment of drug abuse (opioid-dependency))
  - dihydroergotamine and ergotamine (used for migraine headaches)
  - ergometrine (ergonovine) and methylergometrine (methylergonovine) used after giving birth
  - disopyramide, dronedarone, quinidine and dofetilide (used for irregular heart beat rhythms)
  - telithromycin (for pneumonia) when used in patients with severe kidney or liver problems
  - colchicine (for gout) when used in patients with kidney or liver problems
  - halofantrine (for malaria)
  - irinotecan (for cancer)
  - dabigatran (for blood thinning)
  - ticagrelor (for blood clots)
  - quetiapine (for psychosis)
  - aliskiren (for hypertension)
  - darifenacin (for urinary incontinence)
  - 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
  - vardenafil (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** if any of the following symptoms of severe liver problems appear during your course of treatment:

- severe lack of appetite, feeling sick, being sick, unusual tiredness, abdominal (stomach) pain, unusually dark urine or pale stools.

**Tell your doctor immediately if you:**

- have any unusual feelings of tingling, numbness or weakness in your hands or feet whilst taking Itraconazole Oral Solution
- experience any hearing loss symptoms. In very rare cases patients taking itraconazole have reported temporary or permanent hearing loss.

**Tell your doctor if you have:**

- had an allergic reaction to any other antifungal medicines
- a heart problem, including heart failure (also called congestive heart failure or CHF), Itraconazole Oral Solution could make it worse. If your doctor decides to give you Itraconazole, you should be told to watch out for any of the symptoms listed below. **If you get any of the following stop taking Itraconazole Oral Solution and tell your doctor straight away.** These may be signs of heart failure:
  - shortness of breath
  - unexpected weight gain
  - swelling of your legs or stomach
  - feel unusually tired
  - wake up short of breath at night
- a liver problem, such as jaundice (yellowing of the skin), as 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 Oral Solution 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.

- a kidney disorder, as your dose of Itraconazole may have to be changed. In addition, there may be specific medication you may not be able to take.
- a gastro-intestinal disorder that causes slow passage of food through your body. In addition, there may be specific medication you may not be able to take.

**OTHER MEDICINES AND ITRACONAZOLE ORAL SOLUTION**

There are some medicines that **you should not take** whilst taking Itraconazole Oral Solution. These are listed under the heading "**Do not take Itraconazole Oral Solution if you:**

- are taking any of the following medicines"

**Tell your doctor if you are using** the following medicines as they may stop itraconazole from working properly:

- rifampicin, rifabutin and isoniazid (antibiotics used for tuberculosis)
- phenytoin, carbamazepine and phenobarbital (anti-epileptics)
- efavirenz or nevirapine (medicines used for HIV/AIDS)
- St. John's wort (a herbal medicine).

Do not use Itraconazole Oral Solution within 2 weeks of taking these medicines.

**Tell your doctor if you are using** the following medicines as they are not recommended with Itraconazole Oral Solution unless your doctor feels it is necessary:

- medicines for cancer (namely axitinib, dabrafenib, dasatinib, ibritinib, lapatinib, nilotinib, sunitinib or trabectedin)
- simeprevir (for hepatitis C)
- riociguat, when used to treat pulmonary hypertension (increased blood pressure in the blood vessels in the lungs)
- rifabutin (for tuberculosis)
- carbamazepine (for epilepsy)
- colchicine (for gout)
- everolimus or temsirolimus (given after an organ transplant)
- fentanyl (for pain)
- apixaban (for blood clots)
- rivaroxaban (for blood clots)
- salmeterol (for breathing problems)
- tamsulosin (for male urinary incontinence)
- vardenafil (for erectile dysfunction) when used in men 75 years of age and younger
- atorvastatin (for lowering levels of cholesterol)
- ciclesonide (for inflammation, asthma and allergies)
- ebastine (for allergies)
- eletriptan (for migraine headaches)
- tolterodine (for irritated urinary bladder)
- felodipine (for the heart or blood vessels)

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

**Tell your doctor before taking** any of the following medicines as the dose of Itraconazole Oral Solution or other treatments may need to be altered:

- ciprofloxacin, clarithromycin and erythromycin (antibiotics for infections)
- medicines that act on the heart and blood vessels (bosentan, digoxin, nadolol and calcium channel-blockers such as dihydropyridines and verapamil)
- telithromycin (for pneumonia)
- drugs that slow down blood clotting or thin the blood, such as the coumarins (e.g. warfarin) and cilostazol
- methylprednisolone, budesonide, fluticasone and dexamethasone, medicines for inflammation, asthma and allergies
- ciclosporin, tacrolimus and rapamycin (also known as sirolimus), which are usually given after an organ transplant
- medicines used in HIV-infected patients, such as maraviroc, ritonavir, ritonavir-boosted darunavir, ritonavir-boosted fosamprenavir, indinavir and saquinavir
- telaprevir, used in the treatment of Hepatitis C Virus
- medicines for cancer (such as bortezomib, busulphan, docetaxel, erlotinib, gefitinib, imatinib, ixabepilone, ponatinib, trimetrexate and a group of medicines known as vinca alkaloids)
- alfentanil, buprenorphine, sufentanil or oxycodone (for pain)
- methadone for treatment of drug abuse (opioid-dependency)
- buspirone, alprazolam, brotizolam, perospirone and midazolam when given by injection into a vein (for anxiety or to help you sleep)
- reboxetine (for depression)
- loperamide (for diarrhoea)
- repaglinide or saxagliptin (for diabetes)
- aripiprazole, haloperidol or risperidone (for psychosis)
- aprepitant (for nausea and vomiting)
- fesoterodine, oxybutynin or solifenacin (for irritated urinary bladder)
- sildenafil or tadalafil (for erectile dysfunction)
- praziquantel (for fluke and tapeworms)
- bilastine (for allergies)
- meloxicam (for joint inflammation and pain)
- cinacalcet (for an over active parathyroid)
- tolvaptan (for low blood sodium levels)
- alitretinoin (oral) (for eczema)

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

**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 take it one hour before any food or drink as this helps the body absorb the medicine.

**PREGNANCY AND BREAST-FEEDING**

**Pregnancy**

- If you are pregnant, do not take this medicine unless recommended by your doctor.
- If you are of child bearing age and could become pregnant, you should use contraceptives to make sure that you do not become pregnant while you are taking your medicine.
- As itraconazole remains in the body for some time after you stop taking it, you should continue to use some form of contraception until your next period after your treatment has finished.
- If you become pregnant after starting a course of Itraconazole Oral Solution, stop taking it and tell your doctor straight away.
- Before taking any medicine - always tell your doctor if you are pregnant, think you might be pregnant or are trying to become pregnant.

**Breast-feeding**

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

### DRIVING AND USING MACHINES

Itraconazole can sometimes cause dizziness, blurred/double vision or hearing loss. Do not drive or use machines if you have these symptoms.

### Itraconazole Oral Solution contains sorbitol (E420)

This medicine contains 5662 mg sorbitol in each 20ml dose which is equivalent to 283.1 mg/ml.

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

### Itraconazole Oral Solution contains propylene glycol (E1520)

This medicine contains 2072 mg propylene glycol in each 20ml dose which is equivalent to 103.6 mg/ml.

If you are pregnant or breast-feeding, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

If you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

### Itraconazole Oral Solution contains Ethanol

This medicinal product contains a small amount of ethanol (alcohol) less than 100mg per 20ml.

This medicine contains less than 1 mmol sodium (23 mg) per 20ml, that is to say essentially 'sodium-free'.

## 3. HOW TO TAKE ITRACONAZOLE ORAL SOLUTION

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

- Always take the solution one hour before any food or drink as this helps the body absorb the medicine.
- A graduated measuring cup is provided. Ensure you fill the cup to the correct mark.
- You should swish the oral solution around in your mouth for approximately 20 seconds before swallowing it.
- Do not rinse your mouth after swallowing the oral solution.

### Treatment of yeast infections of the mouth, throat or food pipe (oesophagus)

The usual dose is 20 ml per day for one week. This may be taken either all at once or in two divided doses during the day.

If after one week of using the oral solution, your infection has not cleared, your doctor may decide to continue your treatment for one more week.

### Treatment of yeast infections of the mouth, throat or food pipe (oesophagus), that have already been treated with another antifungal but have still not cleared

The usual dose is 10-20 ml twice daily for two weeks. If the infection has not cleared, the treatment may be continued for an additional two weeks. The higher dose of 400mg (40 ml) daily should not be used for more than 14 days if there are no signs of improvement during this time.

### Prevention of fungal infections

The dose is calculated according to your body weight (5 mg per kg) given in two divided doses. Your doctor will tell you exactly how much you should take.

### Use in children and the elderly

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

If you take more Itraconazole Oral Solution than you should contact your doctor or local hospital without delay

If you forget to take Itraconazole Oral Solution, take the next dose as usual and continue your medicine as directed by your doctor. Do not take a double dose to make up for a forgotten dose

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

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, Itraconazole Oral Solution can cause side effects, although not everybody gets them.

### Serious side effects

**Stop taking Itraconazole Oral Solution and contact your doctor immediately** if you have:

- any sudden wheeziness, difficulty in breathing, swelling of the face, rash, itching (especially affecting the whole body). These may be symptoms of a severe hypersensitivity or allergic reaction.
- severe lack of appetite, feeling or being sick, unusual tiredness, abdominal (stomach) pain, unusually dark urine, or pale stools. These may be symptoms of severe liver problems
- severe skin disorder including widespread rashes with blistering and peeling of the skin, mouth, eyes and genitals, or rashes with small pustules or blisters. These rashes can be accompanied by fever, chills, sore throat, tiredness and generally feeling unwell.

**Tell your doctor immediately** if you have any of the side effects below:

- symptoms of heart failure such as shortness of breath, unexpected weight gain, swelling of the legs, unusual fatigue (tiredness), repeated waking at night
- symptoms of nerve damage such as any unusual tingling sensation, numbness or weakness in the limbs
- blurred vision/double vision
- increased sensitivity of the skin to light
- loss of control of urination or increased need to urinate (pass water)
- any symptoms of hearing loss, ringing in your ears.
- severe upper stomach pain, often with nausea and vomiting due to inflammation of the pancreas (pancreatitis)

### Other side effects

Tell your doctor if any of the following symptoms get worse or you are worried.

**Common side effects** (may affect up to 1 in 10 people) are:

- headache
- stomach ache, feeling sick (nausea), being sick (vomiting), diarrhoea, indigestion, unpleasant taste
- rash
- fever or high temperature
- shortness of breath
- dizziness
- cough

**Uncommon side effects** (may affect up to 1 in 100 people) are:

- certain blood disorders which may increase the risk of bleeding, bruising or infections
- muscle cramps or irregular heart beat (possible symptom of low blood levels of potassium)
- constipation
- itching
- general swelling
- hives
- decreased feeling or sensitivity, especially in the skin
- menstrual disorders (abnormal menstrual bleeding or cycle)
- muscle pain, painful joints

**The following side effects have been reported in patients taking itraconazole with not known frequency:**

- excess of triglycerides in the blood
- hair loss
- increase in blood creatine phosphokinase levels

**The following additional side effects have been reported in patients taking itraconazole during clinical trials and with other formulations of Itraconazole**

- infection of the upper respiratory tract
- inflammation of the nose
- inflammation of the sinuses
- certain blood disorder which may increase the risk of infections (possible symptom of low levels of granulocytes)
- high blood sugar levels
- muscle cramps or irregular heart beat (possible symptoms of low blood levels of magnesium)
- muscle cramps or irregular heart beat (possible symptoms of high blood levels of potassium)
- confusion
- sleepiness
- tremors
- increase in heart rate
- high blood pressure
- low blood pressure
- difficulty speaking
- excess gas in the intestinal tract
- increases in specific liver function tests (hepatic enzyme increased)
- inflammation of the liver (hepatitis)
- yellowing of the skin (jaundice)
- excess sweating
- kidney problems
- excessive urine production
- erectile dysfunction
- general swelling
- facial swelling
- chest pain
- pain
- chills
- fatigue
- increase in blood urea level
- abnormal urine findings

### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed below. By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

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**

Ireland

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2

Tel: +353 1 6764971, Fax: +353 1 6762517

Website: [www.hpra.ie](http://www.hpra.ie), e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

## 5. HOW TO STORE ITRACONAZOLE ORAL SOLUTION

### Keep out of the sight and reach of children.

Do not store above 25°C.

Do not use Itraconazole after the expiry date which is stated on the packaging. The expiry date refers to the last day of that month. The oral solution should not be used for longer than 1 month after the bottle has first been opened.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. 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 10mg per ml.
- The other ingredients are hydroxypropyl-β-cyclodextrin, sorbitol (E420), propylene glycol (E1520), cherry flavour, caramel flavour (contains ethanol and propylene glycol), sodium saccharin dihydrate, hydrochloric acid, sodium hydroxide, purified water.

### What Itraconazole Oral Solution looks like and contents of the pack

It is a clear yellow solution, available in bottles containing 150 ml together with a graduated measuring cup, in a cardboard carton.

### Marketing Authorisation Holder

**UK MAH:** Beacon Pharmaceuticals Limited, DCC Vital, Westminster Industrial Estate, Repton Road, Measham, DE12 7DT, England.

**IE MAH:** Athlone Laboratories Limited, Ballymurray, Co. Roscommon, Ireland

### Manufacturer

Kleva S.A., 189 Parnithos Avenue, 136 75 Acharnai Attiki, Greece

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