

## 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 USE Itraconazole Oral Solution if you:

- **are allergic** (hypersensitive) to itraconazole or any of the other ingredients (listed in section 6 Contents of the pack and other information)
- have, or have a history of, congestive heart failure, unless you have a very serious fungal infection
- **are pregnant**, think you might be pregnant or could become pregnant (see the section on Pregnancy)

Do not use this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before using Itraconazole Oral Solution.

Tell your doctor if you are taking any medicines, before you use Itraconazole Oral Solution. **Do not use Itraconazole Oral Solution** if you are taking any of the following medicines, or within 2 weeks of stopping Itraconazole Oral Solution:

#### Medicines to treat problems with the heart, blood or circulation:

- aliskiren, eplerenone, lercanidipine or nisoldipine (for high blood pressure)
- bepridil, ivabradine or ranolazine – (for angina)
- dabigatran or ticagrelor (for blood clots)
- disopyramide, dofetilide, dronedarone or quinidine (for irregular heart beat rhythms)
- finerenone (for kidney problems in patients with type 2 diabetes)
- lomitapide, lovastatin or simvastatin (to lower cholesterol)
- sildenafil (for pulmonary arterial hypertension)

#### Medicines to treat stomach problems or constipation:

- cisapride (used for stomach upsets)
- domperidone (for nausea and vomiting)
- naloxegol (for constipation caused by taking opioid painkillers)

#### Medicines to treat headaches, sleep or mental health problems

- dihydroergotamine and ergotamine (ergot alkaloids used for migraine headaches)
- midazolam (taken by mouth) or triazolam (for sedation or to help you sleep)
- lurasidone, pimozone, quetiapine or sertindole (for schizophrenia, bipolar disorder or other mental health problems)

#### Medicines to treat urinary problems

- darifenacin (for urinary incontinence)
- fesoterodine or solifenacin (for irritated urinary bladder) when used in patients with certain kidney or liver problems,

#### Medicines to treat allergies

- astemizole, mizolastine or terfenadine (for allergies)

#### Medicines to treat erection and ejaculation problems

- avanafil (for erectile dysfunction)
- dapoxetine (for premature ejaculation)
- vardenafil (for erectile dysfunction) when used in men older than 75 years of age

#### Other medicines containing:

- Colchicine (for gout) when used in patients with kidney or liver problems
- ergometrine (ergonovine) and methylethergometrine (methylethergonovine) ergot alkaloids used after giving birth
- eliglustat (for Gaucher’s disease) when used in patients that cannot break down certain medicines in the body
- halofantrine (for malaria)
- irinotecan (for cancer)
- isavuconazole (for fungal infections)
- ombitasvir, paritaprevir, ritonavir with or without dasabuvir – (to treat hepatitis C)
- venetoclax (for chronic lymphocytic leukaemia) when you newly start venetoclax or take increasing doses at the beginning of treatment

**Remember – do not take any of the medicines above for 2 weeks after your last treatment with Itraconazole Oral Solution.**

#### 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.
- Cystic fibrosis (a genetic disease affecting the lungs, pancreas, liver, kidney, and intestines)

#### OTHER MEDICINES AND ITRACONAZOLE ORAL SOLUTION

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. There are some medicines that **you should not take** whilst taking Itraconazole Oral Solution. These are listed above under the heading “**Do not use Itraconazole Oral Solution if you are:**”

**Certain medicines are not recommended for use with Itraconazole Oral Solution.** Your doctor may decide that you **should not take some medicines at the same time as, or within 2 weeks of stopping** Itraconazole Oral Solution.

Examples of these medicines are:

#### Medicines to treat problems with the heart, blood or circulation

- apixaban, edoxaban, rivaroxaban or vorapaxar (for blood clots)
- atorvastatin (to lower cholesterol)
- felodipine (for high blood pressure)
- riociguat or tadalafil (for pulmonary hypertension)

#### Medicines to treat epilepsy, headaches or mental health problems

- phenytoin, carbamazepine or phenobarbital (anti-epileptics)
- eletriptan (for migraine headaches)
- St. John’s Wort (*Hypericum perforatum*) (a herbal medicine used for mental health problems)

#### Medicines to treat urinary problems

- tamsulosin (for male urinary incontinence)
- tolterodine (for irritated urinary bladder)

#### Medicines to treat cancer

- axitinib, bosutinib, cabazitaxel, cabozantinib, ceritinib, cobimetinib, crizotinib, dabrafenib, dasatinib, docetaxel, entrectinib, glasdegib, ibrutinib, lapatinib, nilotinib, olaparib, pazopanib, regorafenib, sunitinib, talazoparib, trabectedin, trastuzumab emtansine, venetoclax (when you are on a stable dose of venetoclax for chronic lymphocytic leukaemia, or at any time of treatment for acute myeloid leukaemia) or vinca alkaloids (e.g., vinflunine, vinorelbine)

#### Medicines to treat tuberculosis

- bedaquiline, isoniazid, rifabutin or rifampicin (for tuberculosis)

#### Medicines to treat human immunodeficiency virus (HIV) or hepatitis

- efavirenz or nevirapine (for HIV/AIDS) elbasvir/grazoprevir, tenofovir alafenamide fumarate (TAF), tenofovir disoproxil fumarate (TDF) (for HIV or hepatitis)

#### Medicines used after organ transplant

- everolimus, rapamycin (also known as sirolimus), temsirolimus

#### Medicines to treat benign prostatic enlargement

- alfuzosin, silodosin

#### Medicines to treat lung problems or allergies

- ciclesonide (for inflammation, asthma and allergies)
- ebastine (for allergies)
- salmeterol (for asthma or chronic obstructive pulmonary disease - COPD)

#### Medicines to treat erection and ejaculation problems

- tadalafil or vardenafil (when used in men 75 years of age and younger) (for erectile dysfunction)

#### Other medicines containing:

- colchicine (for gout)
- fentanyl (for pain)
- lumacaftor/ivacaftor (for cystic fibrosis)

**Remember – do not take any of the medicines above for 2 weeks after your last treatment with Itraconazole Oral Solution.** This is not a complete list, so tell your doctor if you are taking or planning to take any of these medicines, or any other medicines.

**Care needs to be taken when using Itraconazole Oral Solution with certain other medicines** You may be more likely to get side effects, or the dose of Itraconazole Oral Solution or the other medicine might need to be changed.

Examples of these medicines are:

#### Medicines to treat problems with the heart, blood or circulation

- bosentan (for pulmonary hypertension)
- calcium channel blockers such as, dihydropyridines such as amlodipine, isradipine, nifedipine, nimodipine or diltiazem (for hypertension)
- or verapamil (for high blood pressure)
- cilostazol (for circulatory problems)
- ‘coumarins’ such as warfarin (for blood clots)
- digoxin (for atrial fibrillation)
- nadolol (for pulmonary hypertension or angina)

#### Medicines to treat stomach problems or diarrhoea

- aprepitant or netupitant (for nausea and vomiting during cancer treatment)
- loperamide (for diarrhoea)
- antacids such as aluminium, calcium, magnesium, or sodium bicarbonate; H<sub>2</sub>-receptor antagonists such as cimetidine, ranitidine and proton pump inhibitors such as lansoprazole, omeprazole, rabeprazole (to treat stomach acid problems)

#### Medicines to treat sleep problems or mental health problems

- Alprazolam, brotizolam, buspirone, or midazolam (when injected into a vein) (for anxiety or to help you sleep)
- zopiclone (to help you sleep)
- reboxetine or venlafaxine (for depression and anxiety)
- aripiprazole, cariprazine, haloperidol or risperidone (for schizophrenia, bipolar disorder or other mental health problems)
- galantamine (for Alzheimer’s disease)
- guanfacine (for attention deficit hyperactivity disorder)

#### Medicines to treat urinary problems

- imidafenacin, fesoterodine, oxybutynin, solifenacin (for irritated urinary bladder)

#### Medicines to treat cancer

- bortezomib, brentuximab vedotin busulfan, erlotinib, gefitinib, idelalisib, imatinib, nintedanib, panobinostat, pemigatinib, ponatinib, ruxolitinib, sonidegib or tretinoin (oral)

#### Medicines to treat infections

- ciprofloxacin, clarithromycin, or erythromycin (for bacterial infections)
- delamanid (for tuberculosis)
- artemether-lumefantrine or quinine (to treat malaria)
- praziquantel (for fluke and tapeworms)

#### Medicines to treat human immunodeficiency virus (HIV) or hepatitis

- cobicistat, boosted elvitegravir, maraviroc, ritonavir, ritonavir-boosted darunavir, ritonavir-boosted fosamprenavir, indinavir or saquinavir (for HIV)
- glecaprevir/pibrentasvir (for hepatitis)

#### Medicines used after organ transplant

- cyclosporine or tacrolimus

### Medicines to treat benign prostatic enlargement

- dutasteride

### Medicines to treat lung problems, allergies or inflammatory conditions

- bilastine or rupatadine (for allergy)
- methylprednisolone or dexamethasone, (medicines given by mouth or injection for asthma, allergies or inflammatory conditions)
- budesonide or fluticasone (for asthma, allergies)

### Medicines to treat erection and ejaculation problems

- sildenafil (for erectile dysfunction)

### Medicines to treat pain

- alfentanil, buprenorphine, oxycodone or sufentanil (for pain)
- meloxicam (for joint inflammation and pain)

### Other medicines containing:

- alitretinoin (given by mouth) (for eczema)
- cabergoline (for Parkinson's disease)
- cannabis based products including medicines (such as for nausea and vomiting or muscle spasms in patients with multiple sclerosis)
- cinacalcet (for an over active parathyroid)
- dienogest or ulipristal (contraceptives)
- eliglustat (for Gaucher's disease) when used in patients that cannot break down certain medicines in the body
- ivacaftor; (for cystic fibrosis)
- methadone (to treat drug addiction)
- repaglinide or saxagliptin (for diabetes)

This is not a complete list, so tell your doctor if you are taking or planning to take any of these medicines, or any other medicines.

### 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 9880mg sorbitol in each 40ml dose which is equivalent to 247 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 4144mg propylene glycol in each 40ml dose which is equivalent to 103.6 mg/ml.

If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.

If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol.

### Itraconazole Oral Solution contains Cyclodextrins

Itraconazole Oral Solution contains 16000mg cyclodextrin(s) in each 40 mL dose which is equivalent to 400 mg/mL. Cyclodextrins may cause digestive problems such as diarrhoea. There is insufficient information on the effects of cyclodextrin in children

<2 years old. Therefore, a case by case judgement should be made regarding the risk/benefit for the patient with Itraconazole Oral Solution (see section 4.2).

Itraconazole Oral Solution contains less than 1mmol sodium (23mg) per ml, 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

Website: [www.hpra.ie](http://www.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 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:** Kent Pharma UK Limited, 2<sup>nd</sup> Floor, Connect 38, 1 Dover Place, Ashford, Kent, England, TN23 1FB.

**IE MAH:** Athlone Pharmaceuticals Limited, Connaught House, 1 Burlington Road, Dublin 4, Ireland.

### Manufacturer

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

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