

JAMP Itraconazole Oral Solution 10 mg/mL

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What JAMP Itraconazole oral solution is used for

JAMP Itraconazole oral solution is a medicine used:

- to treat yeast infections of the mouth, throat and foodpipe (esophagus) in people with a lowered resistance;
- to prevent certain fungal infections in people who may have a lowered resistance due to a major blood disorder or bone marrow transplantation.

Your doctor may have prescribed JAMP Itraconazole Oral Solution for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

How JAMP Itraconazole Oral Solution works

JAMP Itraconazole works by killing or stopping the growth of the fungus that causes the infection.

Before you take JAMP Itraconazole oral solution

- When you must not take it

Do not take JAMP Itraconazole oral solution:

- if you know you are hypersensitive (allergic) to it;
- if you are pregnant (unless your doctor knows you are pregnant and decides you need JAMP Itraconazole);
- if you are of child-bearing age and could become pregnant, you should take adequate contraceptive precautions to make sure that you do not become pregnant while you are taking your medicine. As JAMP Itraconazole remains in the body for some time after you stop taking it, you should continue to use contraception until your next period after your treatment with JAMP Itraconazole oral solution is finished.
- if you have a condition called heart failure (also called congestive heart failure or CHF), JAMP Itraconazole could make it worse. If your doctor decides that you need to take JAMP Itraconazole even if you have this condition, be sure to get immediate medical help if you have shortness of breath, unexpected weight gain, swelling of the legs, unusual fatigue, or begin to wake up at night.

Also, do not use certain medications if you are on JAMP Itraconazole oral solution. Please refer to the section "Before you start to take it", subsection "Taking other medicines".

Pregnancy and Breastfeeding

Pregnancy

Do not take JAMP Itraconazole oral solution if you are pregnant. If you are of child-bearing age and could become pregnant, you should take adequate contraceptive precautions to make sure that you do not become pregnant while you are taking your medicine. As JAMP 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 with JAMP Itraconazole oral solution is finished.

Breastfeeding

If you are breast-feeding, tell your doctor before taking JAMP Itraconazole oral solution; very small amounts of JAMP Itraconazole could be present in your milk.

- Before you start to take it

Always tell your doctor or pharmacist if you are taking any other medicine because taking some medicines together can be harmful. Tell your doctor if you know you have a liver problem. The dose of JAMP Itraconazole oral solution may need to be adjusted.

Stop taking JAMP Itraconazole oral solution and see your doctor immediately should any of the following symptoms appear during the JAMP Itraconazole oral solution treatment: lack of appetite, nausea, vomiting, tiredness, abdominal pain, yellow color to skin or eyes, pale stools (bowel movements) or very dark urine. If you have to take JAMP Itraconazole oral solution your doctor may also ask you to have your blood

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checked regularly. The reason for this is to rule out liver disorders in timely fashion, since such disorders can occur very rarely.

Tell your doctor if you have a heart problem. Tell your doctor immediately if you develop shortness of breath, unexpected weight gain, swelling of the legs, unusual fatigue, or begin to wake up at night as these may be symptoms of heart failure.

Tell your doctor if you have a kidney disorder. The dose of JAMP Itraconazole oral solution may need to be adjusted.

Tell your doctor or get medical assistance immediately if you have a severe allergic reaction (characterized by significant skin rash, itching, hives, difficulty breathing and/or swollen face) while taking JAMP Itraconazole oral solution.

Stop taking JAMP Itraconazole oral solution and tell your doctor immediately if you become oversensitive to sunlight.

Stop taking JAMP Itraconazole oral solution and tell your doctor immediately if you experience a severe skin disorder such as a widespread rash with peeling skin and blisters in the mouth, eyes and genitals, or a rash with small pustules or blisters.

Stop taking JAMP Itraconazole oral solution and tell your doctor immediately if you develop any feelings of tingling, diminished sensation or weakness in your limbs,

or other problems with the nerves in the arms or legs.

Tell your doctor if you had experienced an allergic reaction to JAMP Itraconazole oral solution or another antifungal.

Tell your doctor if you have cystic fibrosis before using JAMP Itraconazole oral solution.

Stop taking JAMP Itraconazole oral solution and tell your doctor immediately if you experience any hearing loss symptoms. In very rare cases, patients taking JAMP Itraconazole oral solution have reported temporary or permanent hearing loss.

Tell your doctor if your vision gets blurry or you see double, if you hear a ringing in your ears, if you lose the ability to control your urine or urinate much more than usual.

- Taking other medicines

Tell your doctor or pharmacist what medicines you are currently taking. In particular, some medicines must not be taken at the same time, and if certain medicines are taken at the same time, changes need to be made (to the dose, for example).

Medicines that must never be taken while you are on JAMP Itraconazole oral solution:

- terfenadine, astemizole, mizolastine; for allergy;
- bepridil, felodipine, nisoldipine, lercanidipine, ivabradine, ranolazine, eplerenone; to treat angina (crushing chest pain) or high blood pressure;

- cisapride, to treat certain digestive problems;
- simvastatin, lomitapide, lovastatin; which lower the cholesterol;
- midazolam (oral), triazolam; sleeping pills;
- disopyramide, dronedarone, quinidine dofetilide; to treat irregular heart beat rhythms;
- lurasidone, pimozide, sertindole; used for psychotic disorders;
- levacetylmethadol (levomethadyl), methadone; for severe pain or to manage addiction;
- halofantrine; to treat malaria;
- irinotecan, an anti-cancer drug;
- dihydroergotamine or ergotamine (called ergot alkaloids) used in the treatment of migraine headaches;
- ergometrine (ergonovine) or methylergometrine (methylergonovine) (called ergot alkaloids) used to control bleeding and maintain uterine contraction after child birth;
- domperidone; to treat nausea and vomiting;
- isavuconazole; to treat fungal infections;
- naloxegol; to treat constipation caused by taking opioid painkillers;
- avanafil; to treat erectile dysfunction;
- dapoxetine; to treat premature ejaculation.

Medicines that must never be taken while you are on JAMP Itraconazole oral solution, if you have kidney or liver impairment:

- colchicine; to treat gout;
- fesoteridine or solifenacin; when used to control irritated urinary bladder;
- telithromycin; an antibiotic.

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Wait at least 2 weeks after stopping JAMP Itraconazole oral solution before taking any of these medicines.

Medicines that are not recommended, because they can decrease the action of JAMP Itraconazole oral solution:

- carbamazepine, phenytoin, phenobarbital; to treat epilepsy;
- rifampicin, rifabutin, isoniazid; to treat tuberculosis;
- efavirenz, nevirapine; to treat HIV/AIDS.

You should therefore always tell your doctor if you are using any of these products so that the appropriate measures can be taken.

Wait at least 2 weeks after stopping these medicines before taking JAMP Itraconazole oral solution.

Medicines not recommended unless your doctor feels it is necessary:

- axitinib, bosutinib, carbazitaxel, cabozantinib, ceritinib, cobimetinib, crizotinib, dabrafenib, dasatinib, docetaxel, ibrutinib, lapatinib, nilotinib, olaparib, pazopanib, regorafenib, sunitinib, trastuzumab emtansine, vinca alkaloids, trabectedin; used in the treatment of cancer;
- riociguat, sildenafil, tadalafil; when used to treat pulmonary hypertension (increased blood pressure in the blood vessels in the lungs);
- everolimus, rapamycin (also known as sirolimus); usually given after an organ transplant;
- bedaquiline; rifabutin; to treat tuberculosis;
- conivaptan, tolvaptan; to treat low blood sodium;
- apixaban, rivaroxaban; to slow down blood clotting;
- alfuzosin, sildenafil; to treat Benign Prostatic enlargement;
- aliskiren; to treat hypertension;

- carbamazepine; to treat epilepsy;
- colchicine; to treat gout;
- darifenacin; to treat urinary incontinence;
- fentanyl; a strong medicine to treat pain;
- salmeterol; improve breathing;
- simeprevir; to treat hepatitis C;
- tamsulosin; to treat male urinary incontinence;
- vardenafil; to treat erectile dysfunction.
- *Saccharolmyces boulardii*; used to treat diarrhea;
- lumacaftor/ ivacaftor; used to treat Cystic Fibrosis.

Wait at least 2 weeks after stopping JAMP Itraconazole oral solution before starting these medicines unless your doctor feels it is necessary.

Medicines that may require a dose change (for either JAMP Itraconazole oral solution or the other medicine), such as:

- ciprofloxacin, clarithromycin, erythromycin; antibiotics;
- delamanid, used to treat tuberculosis;
- trimetrexate; used to treat pneumonia in patients with immune system problems;
- bosentan, digoxin, nadolol, and certain calcium-channel blockers including verapamil; some medicines that act on the heart or blood vessels;
- guanfacine; used to treat Attention Deficit Hyperactivity Disorder;
- diltiazem; used to treat hypertension;
- coumarins (e.g. warfarin), cilostazol, dabigatran; that slow down blood clotting;
- methylprednisolone, budesonide, ciclesonide, fluticasone or dexamethasone (medicines given by mouth, injection or inhalation for conditions such as inflammations, asthma, and allergies);

- cyclosporine, tacrolimus, temsirolimus, which are usually given after an organ transplant;
- cobicistat, boosted elvitegravir, tenofovir disoproxil fumarate (TDF), maraviroc, and protease inhibitors: indinavir, ritonavir, boosted darunavir, ritonavir-boosted fosamprenavir, saquinavir; used in the treatment of HIV/AIDS;
- dienogest, ulipristal; used as contraceptives;
- boosted asunaprevir, boceprevir, daclatasvir, telaprevir, vaniprevir; used in the treatment of Hepatitis C Virus;
- bortezomib, brentuximab vedotin, busulphan, erlotinib, gefitinib, idelalisib, imatinib, ixabepilone, nintedanib, panobinostat, ponatinib, ruxolitinib, sonidegib, vandetanib; certain medicines used in the treatment of cancer;
- buspirone, perospirone, ramelteon, midazolam IV, alprazolam, brotizolam; for anxiety or to help you sleep (tranquillizer);
- alfentanil, buprenorphine, oxycodone, sufentanil; strong medicines to treat pain;
- repaglinide, saxagliptin; to treat diabetes;
- aripiprazole, cariprazine, haloperidol, quetiapine, risperidone; to treat psychosis;
- suvorexant, zopiclone; to treat insomnia;
- aprepitant, netupitan; to treat nausea and vomiting during cancer treatment;
- loperamide; to treat diarrhea;
- fesoterodine, imidafenacin, solifenacin, tolterodine; certain medicines to control irritated urinary bladder;
- dutasteride; used to treat Benign Prostatic enlargement;
- sildenafil, tadalafil, udenafil; to treat erectile dysfunction;
- praziquantel; to treat fluke and tapeworms;

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- bilastine, ebastine, rupatadine; for allergy;
- reboxetine, venlafaxine; to treat depression and anxiety;
- artemether lumefantrine, quinine; to treat malaria;
- atorvastatin; to lower cholesterol;
- meloxicam; to treat joint inflammation and pain;
- cinacalcet; to treat an over active parathyroid;
- mozavaptan; to treat low blood sodium;
- alitretinoin (oral formulation); to treat eczema;
- cabergoline; to treat Parkinson's Disease;
- cannabinoids; to treat nausea and vomiting, weight loss for patients with immune system problems and muscle spasms in patients with Multiple Sclerosis;
- eletriptan; to treat migraine headaches.
- telithromycin; to treat pneumonia.
- ivacaftor; to treat Cystic Fibrosis.
- galantamine; to treat Alzheimer's disease.
- glecaprevir/pibrentasvir; elbasvir/grazoprevir; ombitasvir/paritaprevir/ritonavir (with or without dasabuvir) combinations, to treat Hepatitis C.

If you know you metabolise drugs that are handled/broken down by the enzyme CYP2D6 very quickly, you should check with your doctor if you can take this medicine as it may require a dose change:

- eliglustat.

Tell your doctor if you are using any of these medicines.

How to take JAMP Itraconazole oral solution

Always take JAMP Itraconazole oral solution without food, because it works better this way.

You are advised not to eat or drink for one hour after taking JAMP Itraconazole oral solution.

- How much to take

For the treatment of yeast infections of the mouth or throat:

Two JAMP Itraconazole oral solution measuring cups per day, taken in 1 intake or divided over 2 intakes, during 1 week. If necessary, your doctor may decide to double the dose or prolong the treatment period.

For the treatment of yeast infections of the foodpipe (esophagus):

One JAMP Itraconazole oral solution measuring cups per day, for a minimum of 3 weeks. If necessary, your doctor may decide to double the dose or prolong the treatment period.

You should swish the solution around in the mouth for approximately 20 seconds before swallowing it and avoid rinsing after taking it.

For the prevention of fungal infections:

0.5 ml of JAMP Itraconazole oral solution per kilogram of body weight per day divided over 2 intakes. Your doctor will tell you exactly how much this means for you.

How to use the measuring cup:

Use the measuring cup just as it sits on the bottle. Make sure that the side with the graduations (the side that holds less) is uppermost; that is the side you have to fill. When the arrow on the side points up, the correct side is uppermost.

- When to take it

Always take JAMP Itraconazole exactly as your doctor has told you. You should check with your doctor if you are not sure.

- How long to take it

Continue taking JAMP Itraconazole for as long as your doctor recommends.

- If you forget to take it

Take the dose you missed as soon as you remember, and then continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you have missed more than one dose, or are not sure what to do, check with your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

- If you take too much (overdose)

Tell your doctor immediately if you have taken too much JAMP Itraconazole oral solution. (S)he will take the necessary measures.

While you are taking JAMP Itraconazole oral solution

- Things you must do

Always follow your doctor's instructions carefully.

If you have to take JAMP Itraconazole Oral Solution continuously for more than 1 month, your doctor may ask you

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to have your blood checked regularly. This is to make sure that your liver is not affected.

If there is any chance of you becoming pregnant, talk to your doctor about the need for an adequate contraception. Once you have finished taking JAMP Itraconazole Oral Solution, you should continue using adequate contraception until you have had your next period. Tell your doctor immediately if you do become pregnant while taking JAMP Itraconazole Oral Solution.

If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking JAMP Itraconazole Oral Solution. Always complete the treatment as directed by your doctor, even if the signs of infection have gone.

- Things you must not do

Do not take JAMP Itraconazole Oral Solution to treat any other complaint unless your doctor says so.

Do not give this medicine to anyone else, even if his or her symptoms seem similar to yours.

- Things to be careful of

Driving and using machines

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

Side effects

Like all medicines, JAMP Itraconazole oral solution can cause side effects, although not everybody gets them. Tell your doctor if you

notice any of the following side effects while using JAMP Itraconazole:

- The following symptoms may occur: upset stomach, nausea, vomiting, diarrhea, abdominal pain, constipation, or excess gas in stomach. Shortness of breath, cough, fluid in the lungs, altered voice, inflammation of the sinuses, inflammation of the nose, upper respiratory tract infection, headache, menstrual disorder, erectile dysfunction, dizziness, confusion, tremor, sleepiness, fatigue, chills, muscle weakness or pain, painful joints, pain, chest pain, swelling, generalized swelling, inflammation of the pancreas, unpleasant taste, fever, excessive sweating, or hair loss may also occur. In addition, increase in heart rate, increase in blood pressure, decrease in blood pressure, or heart failure may also occur. Changes in laboratory tests may occur such as decrease in granulocytes, decrease in white blood cells, decrease in platelets, decrease in blood magnesium, decrease in blood potassium, increase in blood potassium, increase in blood sugar, increase in blood creatine phosphokinase, increase in liver enzymes, increase in blood bilirubin, increase in blood triglycerides, or increase in blood urea.
- Hypersensitivity to JAMP Itraconazole oral solution can occur. It can be recognized, for instance, by skin rash, itching, hives, shortness of breath or difficulty breathing, and/or swollen face. Uncommonly, diminished sensation in the limbs, a tingling sensation in the limbs, or other problems with the nerves in the arms or legs can occur. Very rarely, an oversensitivity to sunlight, or a severe skin disorder (widespread rash with peeling skin and blisters in the mouth, eyes and

genitals, or rash with small pustules or blisters) can occur.

- You may experience one or more of the following symptoms that may be related to heart failure: shortness of breath, unexpected weight gain, swelling of the legs, unusual fatigue, or begin to wake up at night.
- One or more of the following symptoms that may be related to liver disorders may appear: lack of appetite, nausea, vomiting, tiredness, abdominal pain, jaundice, very dark urine and pale stools.
- Your vision could get blurry or you could see double. You could hear a ringing in your ears. You could lose the ability to control your urine or urinate much more than usual. You may experience temporary or permanent hearing loss.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of JAMP Itraconazole oral solution

- Storage

Store at or below 25°C. Keep out of reach of children. This medicine can be kept for only a limited period. Do not use JAMP Itraconazole oral solution after the date (month and year) printed after "EXP", even if it has been stored properly. Discard 28 days after opening.

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- Disposal

Return old medicines to your pharmacist.

Product Description

- What it looks like

The solution comes in a 150 ml bottle with a measuring cup.

- Ingredients

- Active ingredient: Itraconazole
- Inactive ingredients:
Hydroxypropyl- β -cyclodextrin,
sorbitol, propylene glycol,
hydrochloric acid, cherry flavour,
caramel flavour, sodium saccharin,
sodium hydroxide, purified water.

- MAL number:

MALXXX

Manufacturer

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