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Source : U.S. National Library of Medicine

URL of this page: <https://medlineplus.gov/druginfo/meds/a692049.html>

Itraconazole

pronounced as (it'' ra kon' a zole)

IMPORTANT WARNING:

Itraconazole can cause heart failure (condition in which the heart cannot pump enough blood through the body). Tell your doctor if you have or have ever had heart failure. Your doctor may tell you not to take itraconazole. Also tell your doctor if you have or have ever had a heart attack; an irregular heartbeat; or any other type of heart, lung, liver or kidney disease. If you experience any of the following symptoms, stop taking itraconazole and call your doctor immediately: shortness of breath; coughing up white or pink phlegm; weakness; excessive tiredness; fast heartbeat; swelling of the feet, ankles, or legs; waking up at night; and sudden weight gain.

Do not take cisapride (Propulsid) (not available in the U.S.), disopyramide (Norpace), dofetilide (Tikosyn), dronedarone (Multaq), eplerenone (Inspra), ergot-type medications such as dihydroergotamine (D.H.E, Migranal), ergotamine (Ergomar, in Cafergot, in Migergot), methylergometrine (Methergine); felodipine (Plendil), irinotecan (Camptosar), ivabradine (Corlanor), levomethadyl acetate (Orlaam) (not available in the U.S.), lovastatin (Altoprev, in Advicor), lurasidone (Latuda), methadone (Dolophine, Methadose), midazolam (taken by mouth), nisoldipine (Sular), pimozone (Orap), quinidine (in Nuedexta), ranolazine (Ranexa), simvastatin (Zocor, in Simcor, in Vytorin), ticagrelor (Brilinta), and triazolam (Halcion) while taking itraconazole and for 2 weeks afterward. Tell your doctor if you have kidney or liver disease and are taking any of the following medication: colchicine (Colcrys, Mitigare), fesoterodine (Toviaz), solifenacin (Vesicare), or telithromycin (Ketek). Taking these medications with itraconazole can cause serious heart problems including QT prolongation (an irregular heart rhythm that can lead to fainting, loss of consciousness, seizures, or sudden death).

Talk to your doctor about the risks of taking itraconazole.

Why is this medication prescribed?

Itraconazole capsules are used to treat fungal infections in the lungs that can spread throughout the body. Itraconazole capsules are also used to treat fungal infections of the fingernails. Itraconazole tablets and capsules are used to treat fungal infections of the toenails. Itraconazole oral solution (liquid)

is used to treat yeast infections of the mouth and throat or of the esophagus (tube that connects the throat to the stomach). Itraconazole is in a class of antifungals called triazoles. It works by slowing the growth of fungi that cause infection.

How should this medicine be used?

Itraconazole comes as a capsule, a tablet, and a solution (liquid) to take by mouth. If you are taking itraconazole to treat fungal infections in the lungs, the capsules are usually taken during or right after a full meal one or two times a day for at least 3 months. However, if you are taking itraconazole to treat a serious fungal infection in the lungs, the capsules may be taken with a meal three times a day for the first 3 days of treatment and then taken once or twice a day with a meal for at least 3 months. If you are taking itraconazole to treat fungal infections of the toenails (including or without fingernail infections), the capsules or tablets are usually taken once a day with a full meal for 12 weeks. If you are taking itraconazole to treat fungal infections of the fingernails only, the capsules are usually taken twice a day with a full meal for 1 week, skipped for 3 weeks, and then taken twice a day with a meal for a week. Itraconazole oral solution is usually taken on an empty stomach once or twice a day for 1 to 4 weeks or sometimes longer. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take itraconazole exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow itraconazole capsules whole; do not open, chew, or crush them.

Your doctor may tell you to take itraconazole capsules with a cola soft drink if you have certain medical conditions or are taking any of the following medications: cimetidine; famotidine (Pepcid); nizatidine (Axid); proton-pump inhibitors such as esomeprazole (Nexium, in Vimovo), lansoprazole (Prevacid, in Prevpac), omeprazole (Prilosec, in Zegerid), pantoprazole (Protonix), rabeprazole (AcipHex), or ranitidine (Zantac). Follow these directions carefully.

To take itraconazole oral solution for fungal infections of the mouth or throat, swish 10 milliliters (about 2 teaspoons) of the solution in your mouth for several seconds and swallow. Repeat if necessary to take your entire dose.

Itraconazole capsules and oral solution are absorbed into the body in different ways and work to treat different conditions. Do not substitute the capsules for the liquid or the liquid for the capsules. Be sure that your pharmacist gives you the itraconazole product that your doctor prescribed.

If you are taking itraconazole to treat a nail infection, your nails will probably not look healthier until new nails grow. It can take up to 6 months to grow a new fingernail and up to 12 months to grow a new toenail, so you should not expect to see improvement during your treatment or for several months afterward. Continue to take itraconazole even if you do not see any improvement.

Continue to take itraconazole until your doctor tells you to stop even if you feel well. Do not stop taking itraconazole without talking to your doctor. If you stop taking itraconazole too soon, your infection may come back after a short time.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

Other uses for this medicine

Itraconazole is also sometimes used to treat other types of fungal infections and to prevent fungal infections in people who have human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS). Talk to your doctor about the possible risks of using this drug for your condition.

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking itraconazole,

- tell your doctor and pharmacist if you are allergic to itraconazole; other antifungal medications such as fluconazole (Diflucan), ketoconazole (Nizoral), or voriconazole (Vfend); any other medications, or any of the ingredients in itraconazole products. If you are taking itraconazole oral solution, tell your doctor if you are allergic to saccharin or sulfa medications. Ask your pharmacist for a list of the ingredients.
- tell your doctor and pharmacist if you are taking the following medications or took them in the last 2 weeks before starting treatment with itraconazole: carbamazepine (Epitol, Tegretol, Teril, others); efavirenz (Sustiva, in Atripla); isoniazid (Laniazid, in Rifamate, in Rifater); rifabutin (Mycobutin); rifampicin; nevirapine (Viramune); phenobarbital; and phenytoin (Dilantin, Phenytek).
- tell your doctor or pharmacist if you are taking the following medications: aliskiren (Tekturna, in Amturnide, Tekamlo, and Tekturna HCT), apixaban (Eliquis), axitinib (Inlyta), colchicine (Colcrys, Mitigare), dabrafemob (Tafinlar), darifenacin (Enablex), dasatinib (Sprycel), everolimus (Afinitor, Zortress), ibrutinib (Imbruvica), nilotinib (Tasigna), rivaroxaban (Xarelto), salmeterol (Serevent), sildenafil (only Revatio brand used for lung disease), simeprevir (Olysio), sunitinib (Sutent), tamsulosin (Flomax, in Jalyn), temsirolimus (Torisel), trabectedin (Yondelis), and vardenafil (Staxyn, Levitra). Your doctor may tell you not to take these medications during your treatment and for 2 weeks after your treatment with itraconazole.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements and herbal products you are taking or plan to take. Be sure to mention the medications listed in the IMPORTANT WARNING section and any of the following: antibiotic medications such as ciprofloxacin (Cipro), clarithromycin (Biaxin, in PrevPac), erythromycin (E.E.S. Ery-Tab, others), and telithromycin (Ketek); anticoagulant ("blood thinner") such as warfarin (Coumadin, Jantoven); alprazolam (Xanax); aprepitant (Emend); aripiprazole (Abilify); atorvastatin (Lipitor, in Caduet, in Liptruzet); bortezomib (Velcade); bosentan (Tracleer); budesonide (Entocort EC, Pulmicort, Uceris); buprenorphine (Buprenex, Butrans, in Bunavail; others); buspirone; ciclesonide (Alvesco, Omnaris, Zetonna); cilostazol (Pletal); cinacalcet (Sensipar); cyclosporine (Gengraf, Neoral, Sandimmune); dabigatran (Pradaxa); dexamethasone; diazepam (Valium); digoxin (Lanoxin); docetaxel (Docefrez, Taxotere); eletriptan (Relpax); erlotinib (Tarceva); fentanyl (Actiq, Duragesic, Fentora, Subsys, others); fesoterodine (Toviaz); fluticasone (Flovent, in Advair); gefitinib (Iressa); haloperidol (Haldol); HIV protease inhibitors including indinavir (Crixivan), darunavir (Prezista) taken with ritonavir, fosamprenavir (Lexiva) taken with ritonavir, and saquinavir (Invirase); imatinib (Gleevec); ixabepilone (Ixempra Kit); lapatinib (Tykerb); maraviroc (Selzentry); meloxicam (Mobic); methylprednisolone (Medrol); nadolol (Corgard, in Corzide); oxybutynin (Ditropan XL, Oxytrol); oxycodone (Oxaydo, Oxycontin, in Percodan; others); ponatinib (Iclusig); praziquantel (Biltricide); quetiapine (Seroquel); ramelteon (Rozerem); repaglinide (Prandin, in Prandimet); riociguat (Adempas); risperidone (Risperdal); saxagliptin (Kombiglyze XR, Onglyza); sirolimus (Rapamune); solifenacin (Vesicare); tacrolimus (Astagraf, Prograf); tadalafil (Adcirca, Cialis); tolterodine (Detrol); vardenafil (Levitra, Staxyn); verapamil (Calan, Covera, Verelan PM, in Tarka), vinblastine, vincristine (Marqibo Kit), and vinorelbine (Navelbine). Your doctor may need to change

the doses of your medications or monitor you carefully for side effects. Many other medications may also interact with itraconazole, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on these lists.

- if you are taking an antacid, take it 1 hour before or 2 hours after you take itraconazole.
- tell your doctor if you have or have ever had the conditions mentioned in the **IMPORTANT WARNING** section,, cystic fibrosis (an inborn disease that causes problems with breathing, digestion, and reproduction), any condition that decreases the amount of acid in your stomach, or HIV.
- tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding. You should not take itraconazole to treat nail fungus if you are pregnant or could become pregnant. You may start to take itraconazole to treat nail fungus only on the second or third day of your menstrual period when you are sure you are not pregnant. You must use effective birth control during your treatment and for 2 months afterward. If you become pregnant while taking itraconazole to treat any condition, call your doctor.
- you should know that itraconazole may make you dizzy or cause blurred or double vision. Do not drive a car or operate machinery until you know how this medication affects you.

What special dietary instructions should I follow?

Talk to your doctor about drinking grapefruit juice while taking this medication.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Itraconazole may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- diarrhea
- constipation
- gas or bloating
- heartburn
- unpleasant taste
- sore or bleeding gums
- headache
- dizziness
- sweating
- muscle pain or weakness
- joint pain

- decreased sexual desire or ability
- nervousness
- depression
- runny nose and other cold symptoms
- fever
- hair loss

Some side effects can be serious. If you experience any of these symptoms, call your doctor immediately:

- blurred vision or double vision
- ringing in the ears
- inability to control urination or urinating more than usual

If you experience any of the following symptoms or those listed in the IMPORTANT WARNING section, stop taking itraconazole and call your doctor immediately or get emergency medical treatment:

- excessive tiredness
- loss of appetite
- nausea
- stomach pain
- vomiting
- yellowing of the skin or eyes
- dark urine
- pale stools
- feelings of numbness, tingling, pricking, burning, or creeping on the skin
- hearing loss
- increased sensitivity to light
- severe skin disorder
- hearing loss
- rash
- hives
- itching
- swelling of the face, throat, tongue, lips, eyes, hands, ankles, or lower legs
- hoarseness
- difficulty breathing or swallowing

One of the ingredients in itraconazole oral solution caused cancer in some types of laboratory animals. It is not known whether people who take itraconazole solution have an increased risk of developing cancer. Talk to your doctor about the risks of taking itraconazole solution.

Itraconazole may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat, light, and moisture (not in the bathroom).

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests to check your response to itraconazole.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription. If you still have symptoms of infection after you finish the itraconazole, call your doctor.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Onmel[®]
- Sporanox[®]

Last Revised - 11/15/2017

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National Library of Medicine 8600 Rockville Pike, Bethesda, MD 20894 U.S. Department of Health and Human Services

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Page last updated: 25 March 2022