

# Itraconazole (IT-ra-KON-a-zole) Capsules

## Rx only

This summary contains important information about itraconazole.

This information is for patients who have been prescribed itraconazole to treat fungal nail infections. **If your doctor prescribed itraconazole for medical problems other than fungal nail infections, ask your doctor if there is any information in this summary that does not apply to you.** Read this information carefully each time you start to use itraconazole. This information does not take the place of discussion between you and your doctor. Only your doctor can decide if itraconazole is the right treatment for you. If you do not understand some of this information or have any questions, talk with your doctor or pharmacist.

### WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT ITRACONAZOLE?

Itraconazole is used to treat fungal nail infections. However, itraconazole is not for everyone. **Do not take itraconazole for fungal nail infections if you have had heart failure, including congestive heart failure. You should not take itraconazole if you are taking certain medicines that could lead to serious or life-threatening medical problems.**

(See “Who Should Not Take Itraconazole?” below.)

If you have had heart, lung, liver, kidney or other serious health problems, ask your doctor if it is safe for you to take itraconazole.

### WHAT HAPPENS IF I HAVE A FUNGAL NAIL INFECTION?

Anyone can have a fungal nail infection, but it is usually found in adults. When a fungus infects the tip or sides of a nail, the infected part of the nail may turn yellow or brown. If not treated, the fungus may spread under the nail towards the cuticle. If the fungus spreads, more of the nail may change color, may become thick or brittle, and the tip of the nail may become raised. In some patients, this can cause pain and discomfort.

### WHAT IS ITRACONAZOLE?

Itraconazole is a prescription medicine used to treat fungal infections of the toenails and fingernails. It is also used to treat some types of fungal infections in other areas of your body. We do not know if itraconazole works in children with fungal nail infections or if it is safe for children to take.

Itraconazole comes in the form of capsules and liquid (oral solution). The capsule and liquid forms work differently, so you should not use one in place of the other. This Patient Information discusses only the capsule form of itraconazole. You will get these capsules in a medicine bottle or carton or 7 Day Treatment Pack. The 7 Day Treatment Pack contains 28 capsules for treatment of your fungal nail infection.

Itraconazole goes into your bloodstream and travels to the source of the infection underneath the nail so that it can fight the infection there. Improved nails may not be obvious for several months after the treatment period is finished because it usually takes about 6 months to grow a new fingernail and 12 months to grow a new toenail.

### WHO SHOULD NOT TAKE ITRACONAZOLE?

Itraconazole are not for everyone. Your doctor will decide if itraconazole is the right treatment for you. **Some patients should not take itraconazole because they may have certain health problems or may be taking certain medicines that could lead to serious or life-threatening medical problems.**

Tell your doctor and pharmacist the name of all the prescription and non-prescription medicines you are taking, including dietary supplements and herbal remedies. Also tell your doctor about any other medical conditions you have had, especially heart, lung, liver or kidney conditions; or if you have cystic fibrosis, or have had an allergic reaction to itraconazole or any other antifungal medicines.

**Never** take itraconazole if you:

- have had heart failure, including congestive heart failure.
- are taking any of the medicines listed below. Dangerous or even life-threatening side effects could result:
  - avanafil (such as Stendra™)
  - cisapride (such as Propulsid®)
  - colchicine (such as Colcrys™) [if you also have pre-existing kidney or liver impairment]
  - disopyramide (such as Norpace®)
  - dofetilide (such as Tikosyn™)
  - eliglustat (such as Cerdelga™) [if you know you do not break down drugs that are broken down by the enzyme CYP 2D6]
  - dronedarone (such as Multaq®)
  - eplerenone (such as Inspra®)
  - ergot alkaloids (such as Migranal®, Ergonovine, Cafergot®, Methergine®)
  - felodipine (such as Plendil®)
  - fesoterodine (such as Toviaz®) [if you also have pre-existing kidney or liver impairment]
  - irinotecan (such as Camptosar®)
  - isavuconazole (such as Cresemba®)
  - ivabradine (such as Corlanor®)
  - lomitapide (such as Juxtapid™)
  - lovastatin (such as Mevacor®, Advicor®, Altacor™)
  - lurasidone (such as Latuda®)
  - methadone (such as Dolophine®)
  - midazolam (such as Versed®)

- naloxegol (such as Movantik<sup>®</sup>)
- nisoldipine (such as Sular<sup>®</sup>)
- pimozide (such as Orap<sup>®</sup>)
- quinidine (such as Cardioquin<sup>®</sup>, Quinaglute<sup>®</sup>, Quinidex<sup>®</sup>)
- ranolazine (such as Ranexa<sup>®</sup>)
- simvastatin (such as Zocor<sup>®</sup>)
- solifenacin (such as Vesicare<sup>®</sup>) [if you also have pre-existing kidney or liver impairment]
- telithromycin (such as Ketek<sup>®</sup>) [if you also have pre-existing kidney or liver impairment]
- ticagrelor (such as Brilinta<sup>®</sup>)
- triazolam (such as Hacion<sup>®</sup>)
- have ever had an allergic reaction to itraconazole.

Taking itraconazole with certain other medicines may lead to serious or life-threatening medical problems. Tell your doctor and pharmacist the name of all the prescription and non-prescription medicines you are taking, including dietary supplements and herbal remedies. Your doctor will decide if itraconazole is the right treatment for you.

**WHAT SHOULD I KNOW ABOUT ITRACONAZOLE AND PREGNANCY OR BREAST FEEDING?**

Never take itraconazole if you have a fungal nail infection and are pregnant or planning to become pregnant within 2 months after you have finished your treatment.

If you are able to become pregnant, you should use effective birth control during itraconazole treatment and for 2 months after finishing treatment. Ask your doctor about effective types of birth control.

If you are breast-feeding, talk with your doctor about whether you should take itraconazole.

**HOW SHOULD I TAKE ITRACONAZOLE CAPSULES?**

Always take itraconazole capsules during or right after a full meal.

Your doctor will decide the right dose for you. Depending on your infection, you will take itraconazole once a day for 12 weeks, or twice a day for 1 week in a “pulse” dosing schedule. You will receive either a bottle of capsules or a carton of capsules or a 7 Day Treatment Pack. Do not skip any doses. Be sure to finish all your itraconazole as prescribed by your doctor.

If you have ever had liver problems, your doctor should do a blood test to check your condition. If you haven’t had liver problems, your doctor may recommend blood tests to check the condition of your liver because patients taking itraconazole can develop liver problems.

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

If you forget to take or miss doses of itraconazole, ask your doctor what you should do with the missed doses.

**THE ITRACONAZOLE 7 DAY TREATMENT PACK**

If you use the 7 Day Treatment Pack, you will take itraconazole for 1 week and then take no itraconazole for the next 3 weeks before repeating the 1-week treatment. This is called “pulse dosing.” The itraconazole 7 Day Treatment Pack contains enough medicine for one “pulse” (1 week of treatment).

The itraconazole 7 Day Treatment Pack comes with special instructions. It contains 7 blisters and each blister contains 4 capsules.

- Take 2 capsules in the morning and 2 capsules in the evening. This means you will take 4 capsules a day for 7 days. At the end of 7 days, you will have taken all of the capsules in the 7 Day Treatment Pack.
- After you finish the 7 Day Treatment Pack, do not take any itraconazole for the next 3 weeks. Even though you are not taking any capsules during this time, itraconazole keeps working inside your nails to help fight the fungal infection.
- You will need more than one “pulse” to treat your fungal nail infection. When your doctor prescribes another pulse treatment, be sure to get your refill before the end of week 4.

Itraconazole Pulse Dosing														
Take 2 Itraconazole Capsules twice a day for 1 week														
	Day 1		Day 2		Day 3		Day 4		Day 5		Day 6		Day 7	
	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
Week 1	//	//	//	//	//	//	//	//	//	//	//	//	//	//
Week 2	<p style="text-align: center;"><b>For the next 3 weeks, do not take any Itraconazole Capsules.</b> Remember to get a refill before the end of Week 4 when your doctor prescribes another <i>7 Day Treatment Pack</i></p>													
Week 3														
Week 4														

**WHAT ARE THE POSSIBLE SIDE EFFECTS OF ITRACONAZOLE?**

The most common side effects include: headache, and digestive system problems (such as nausea, and abdominal pain).

**Stop itraconazole and call your doctor or get medical assistance right away** if you have a severe allergic reaction. Symptoms of an allergic reaction may include skin rash, itching, hives, shortness of breath or difficulty breathing, and/or swelling of the face. Very rarely, an oversensitivity to sunlight, a tingling sensation in the limbs or a severe skin disorder can occur. If any of these symptoms occur, stop taking itraconazole and contact your doctor.

**Stop itraconazole and call your doctor right away** if you develop shortness of breath; have unusual swelling of your feet, ankles or legs; suddenly gain weight; are unusually tired; cough up white or pink phlegm; have unusual fast heartbeats; or begin to wake up at night. In rare cases, patients taking itraconazole could develop serious heart problems, and these could be warning signs of heart failure.

**Stop itraconazole and call your doctor right away** if you become unusually tired; lose your appetite; or develop nausea, abdominal pain, or vomiting, a yellow color to your skin or eyes, or dark colored urine or pale stools (bowel movements). In rare cases, patients taking itraconazole could develop serious liver problems and these could be warning signs.

**Stop itraconazole and call your doctor right away** if you experience any hearing loss symptoms. In very rare cases, patients taking itraconazole have reported temporary or permanent hearing loss.

**Call your doctor right away** if you develop tingling or numbness in your extremities (hands or feet), 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.

Additional possible side effects include upset stomach, vomiting, constipation, fever, inflammation of the pancreas, menstrual disorder, erectile dysfunction, dizziness, muscle pain, painful joints, unpleasant taste, or hair loss. These are not all the side effects of itraconazole. Your doctor or pharmacist can give you a more complete list.

#### **WHAT SHOULD I DO IF I TAKE AN OVERDOSE OF ITRACONAZOLE?**

If you think you took too much itraconazole, call your doctor or local poison control center, or go to the nearest hospital emergency room right away.

#### **HOW SHOULD I STORE ITRACONAZOLE?**

Keep all medicines, including itraconazole, out of the reach of children.

Store itraconazole capsules and 7 Day Treatment Pack at room temperature in a dry place away from light.

#### **GENERAL ADVICE ABOUT ITRACONAZOLE**

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use itraconazole for a condition for which it was not prescribed. Do not give itraconazole to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about itraconazole. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about itraconazole that is written for health professionals.

Call your doctor for medical advice about side effects. You may report side effects to Alembic Pharmaceuticals Limited at 1-866-210-9797 or FDA at 1-800-FDA-1088.

This patient information has been approved by the U.S. Food and Drug Administration.

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Medication Guide available at <http://www.alembicusa.com/medicationguide.aspx> or call 1-866-210-9797.

Manufactured by:

**Alembic Pharmaceuticals Limited**

(Formulation Division),

Panelav 389350, Gujarat, India

Manufactured for:

**Alembic Pharmaceuticals, Inc.**

750 Route 202, Bridgewater, NJ 08807

USA

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