

PATIENT INFORMATION

Itraconazole (IT-ra-KON-a-zole) Capsules, USP

Read this Patient Information that comes with itraconazole capsules before you start taking it and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about itraconazole capsules?

Itraconazole capsules can cause serious side effects, including:

1. **Heart failure.** Do not take itraconazole capsules if you have had heart failure, including congestive heart failure.

Stop taking itraconazole capsules and call your healthcare provider right away if you have any of these symptoms of congestive heart failure:

- shortness of breath
- swelling of your feet, ankles or legs
- sudden weight gain
- increased tiredness
- coughing up white or pink mucus (phlegm)
- fast heartbeat
- waking up at night more than normal for you

2. **Heart problems and other serious medical problems.** Serious medical problems that affect the heart and other parts of your body can happen if you take itraconazole capsules with certain other medicines. **Do not take itraconazole capsules if you also take the following medicines:**

- | | | |
|---|------------------|--------------------------|
| • methadone | • irinotecan | • naloxegol |
| • disopyramide | • lurasidone | • lomitapide |
| • dofetilide | • oral midazolam | • lovastatin |
| • dronedarone | • pimozide | • simvastatin |
| • quinidine | • triazolam | • avanafil |
| • isavuconazole | • felodipine | • ticagrelor |
| • ergot alkaloids (such as dihydroergotamine, ergometrine ergonovine) | • nisoldipine | • venetoclax (see below) |
| • ergotamine | • ivabradine | • finerenone |
| • methylergometrine (methylergonovine) | • ranolazine | • voclosporin |
| | • eplerenone | |
| | • cisapride | |

Do not take itraconazole capsules with venetoclax for chronic lymphocytic leukemia/small lymphocytic lymphoma when you first start treatment with venetoclax or with increasing doses of venetoclax.

This is not a complete list of medicines that can interact with itraconazole capsules. Itraconazole capsules may affect the way other medicines work, and other medicines may affect how itraconazole capsules works. You can ask your pharmacist for a list of medicines that interact with itraconazole capsules.

Before you start taking itraconazole capsules, tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Before you start any new medicine, ask your healthcare provider or pharmacist if it is safe to take it with itraconazole capsules.

3. **Liver problems.** Itraconazole capsules can cause serious liver problems which may be severe and lead to death. **Stop taking itraconazole capsules and call your healthcare provider right away if you have any of these symptoms of liver problems:**

- tiredness
- loss of appetite for several days or longer
- nausea or vomiting
- dark or "tea-colored" urine
- your skin or the white part of your eyes turn yellow (jaundice)
- light-colored stools (bowel movement)

For more information about side effects, see "What are the possible side effects of itraconazole capsules?"

What is itraconazole capsule?

- Itraconazole capsule is a prescription medicine used to treat the following fungal infections of the toenails, fingernails and other parts of the body: blastomycosis, histoplasmosis, aspergillosis, and onychomycosis.
- It is not known if itraconazole capsule is safe and effective in children.

Do not take itraconazole capsule if you:

- have or have had heart failure, including congestive heart failure.
- take certain medicines. See "What is the most important information I should know about itraconazole capsules?"
- are pregnant or plan to become pregnant. Itraconazole capsules can harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking itraconazole capsules. Females who are able to become pregnant must use effective forms of birth control during treatment and for 2 months after stopping treatment with itraconazole capsules.
- are allergic to itraconazole or any of the ingredients in itraconazole capsules. See the end of this Patient Information leaflet for a complete list of ingredients in itraconazole capsules.

Before taking itraconazole capsules, tell your healthcare provider about all of your medical conditions, including if you:

- have heart problems.
- have liver problems.
- have kidney problems.
- have a weakened immune system (immunocompromised).
- have lung problems including cystic fibrosis.
- are breastfeeding or plan to breastfeed. Itraconazole can pass into your breast milk. You and your healthcare provider should decide if you will take itraconazole capsules or breastfeed.

Taking itraconazole capsules with certain medicines may affect each other. Taking itraconazole capsules with other medicines can cause serious side effects.

How should I take itraconazole capsules?

- Take itraconazole capsules exactly as prescribed by your healthcare provider. Your healthcare provider will tell you how much itraconazole capsules to take and when to take it.
- You will receive itraconazole capsules in a blister pack or bottle. Your healthcare provider will decide the type of itraconazole capsules that is right for you.
- Take itraconazole capsules with a full meal.
- Swallow itraconazole capsules whole.
- You should not take itraconazole oral solution instead of itraconazole capsules, because they will not work the same way.
- If you take too much itraconazole capsules, call your healthcare provider or go to the nearest hospital emergency room right away.

What should I avoid while taking itraconazole capsules?

Itraconazole capsules can cause dizziness and vision problems. Do not drive or operate machinery until you know how itraconazole capsule affects you.

What are the possible side effects of itraconazole capsules?

Itraconazole capsules may cause serious side effects, including:

- See “**What is the most important information I should know about itraconazole capsules?**”
- **New or worsening high blood pressure and low potassium levels in your blood (pseudoaldosteronism).** Your healthcare provider should check your blood pressure and potassium levels.
- **Nerve problems (neuropathy).** Call your healthcare provider right away if you have tingling or numbness in your hands or feet. Your healthcare provider may stop your treatment with itraconazole capsules if you have nerve problems.
- **Hearing loss.** Hearing loss can happen for a short time or permanently in some people who take itraconazole capsules. Stop taking itraconazole capsules and call your healthcare provider right away if you have any changes in your hearing.

The most common side effects of itraconazole capsules include: headache, rash, digestive system problems (such as nausea and vomiting), and edema.

Additional possible side effects include upset stomach, constipation, fever, inflammation of the pancreas, increase in blood pressure, menstrual disorder, erectile dysfunction, dizziness, muscle pain, painful joints, unpleasant taste, or hair loss.

These are not all the possible side effects of itraconazole capsules.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store itraconazole capsules?

- Store itraconazole capsules at room temperature between 15° to 25°C (59° to 77°F).
- Bottle of 30's count and 90's count come in a child-resistant package.
- Keep itraconazole capsules dry and away from light.

Keep itraconazole capsules and all medicines out of the reach of children.

General information about the safe and effective use of itraconazole capsules.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use itraconazole capsules for a condition for which it was not prescribed. Do not give itraconazole capsules to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your doctor or pharmacist for information about itraconazole capsules that is written for health professionals.

What are the ingredients in itraconazole capsules?

Active ingredients: itraconazole (coated on sugar spheres composed of purified water, starch and sucrose)

Inactive ingredients: D&C Red No. 22, D&C Red No. 28, FD&C Blue No. 1, gelatin, hydroxypropyl methylcellulose, polyethylene glycol, and titanium dioxide. The imprinting ink contains black iron oxide, potassium hydroxide, propylene glycol, and shellac.

Manufactured by:

Alembic Pharmaceuticals Limited

(Formulation Division),

Panelav 389350, Gujarat, India

Manufactured for:

Alembic Pharmaceuticals, Inc.

Bedminster, NJ 07921, USA

For more information or call 1-866-210-9797.

20043054