

ITRANOX

Itraconazole capsules

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about ITRANOX. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using ITRANOX against the benefits it is expected to have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT ITRANOX IS USED FOR

ITRANOX capsules are used to treat certain fungal infections which include the following:

- persistent infections of the nails, skin, hands, feet or groin;
- persistent candida (yeast) infections of the vagina;
- eye infections which have not responded to other treatment or which may be affecting vision;
- candida (yeast) infections of the mouth or throat in patients with lower resistance to disease;
- generalised infections.

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

Your doctor may have prescribed ITRANOX capsules for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

BEFORE YOU USE ITRANOX

When you must not take it

Do not take ITRANOX capsules if:

- you are pregnant or may become pregnant.
- you have a condition called heart failure (also called congestive heart failure or CHF), ITRANOX could make it worse. If your doctor decides that you need to take ITRANOX 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.
- you have an allergy to ITRANOX capsules or any of the ingredients. See Product Description at the end of this leaflet.

Do not take ITRANOX capsules with any of the following:

- certain medicines for allergy or hay fever (terfenadine, astemizole or mizolastine);
- certain medicines used to treat angina (crushing chest pain) and high blood pressure, namely bepridil or nisoldipine;
- domperidone (used to treat nausea and vomiting);

- ticagrelor (used for the prevention of heart attack or stroke);
- solifenacin(used to treat urinary incontinence);
- cisapride (used for certain digestive problems);
- certain medicines used to produce calmness or to help you sleep (midazolam or triazolam);
- certain HMG-CoA reductase inhibitors, such as simvastatin or lovastatin (used to lower your cholesterol);
- pimoziide or sertindole (used to treat mental disorders);
- quinidine or dofetilide (used to treat irregular heart beats);
- levacetylmethadol (used to treat opioid-dependency);
- dihydroergotamine and ergotamine (used to treat migraine);
- ergometrine or methylergometrine (used to control bleeding and maintain uterine contraction after child birth).

Do not take ITRANOX capsules if the packaging is torn or shows signs of tampering.

Do not take ITRANOX capsules beyond the expiry date (month and year) printed on the pack.

Before you start to take it

You must tell your doctor if:

- you are breast feeding or wish to breastfeed;
- you have had an allergic reaction to other medicines used to treat fungal infections;
- you have or have had any liver problems;
- you have or have had any kidney problems;
- you have heart problems
- you are a neutropenic, AIDS or an organ transplant patient.
- you are a cystic fibrosis patient.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking or are given ITRANOX capsules.

Your doctor will advise whether or not to take ITRANOX or if you need to adjust the dose or adapt your treatment.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines you can buy without a prescription from a pharmacy, supermarket or health food shop.

In particular, ITRANOX capsules must not be taken with some medicines. Examples are:

- certain medicines for allergy or hay fever (terfenadine, astemizole or mizolastine);
- certain medicines for angina or high blood pressure, namely bepridil or nisoldipine;
- cisapride (used for certain digestive problems);

- certain medicines used to produce calmness or to help you sleep (midazolam or triazolam);
- certain HMG-CoA reductase inhibitors, such as simvastatin or lovastatin (used to lower your cholesterol);
- pimoziide or sertindole (used to treat mental disorders);
- quinidine or dofetilide (used to treat irregular heart beats);
- levacetylmethadol (used to treat opioid-dependency);
- dihydroergotamine and ergotamine (used to treat migraine);
- ergometrine or methylergometrine (used to control bleeding and maintain uterine contraction after child birth).

Certain medicines may be affected by ITRANOX capsules or may affect how well ITRANOX capsules work. Your doctor may need to adjust the dose or adapt your treatment.

Examples of these medicines are:

- anticoagulants such as apixaban (used to slow blood clotting);
- simeprevir and telaprevir as HCV protease inhibitors (used to treat hepatitis C);
- certain antineoplastics such as sunitinib (used to treat certain types of stomach, bowel, or esophagus tumor and kidney or pancreatic cancer);
- rifampicin, rifabutin or isoniazid (used to treat tuberculosis);
- phenytoin, phenobarbital or carbamazepine (used to treat fits);
- clarithromycin, erythromycin (antibiotics);
- certain medicines used to treat AIDS, such as indinavir, saquinavir and ritonavir;
- certain calcium channel blockers (used to treat heart or blood pressure problems);
- digoxin (used to treat heart failure);
- cyclosporin, sirolimus, tacrolimus (used to help prevent organ transplant rejection or to treat certain problems with the immune system);
- some contraceptive pills (birth control pills);
- busulphan, vinca alkaloids, docetaxel (used to treat some cancers);
- methylprednisolone, budesonide, fluticasone and dexamethasone (often used for conditions such as inflammations, asthma and allergies);
- trimetrexate (used to treat certain type of pneumonia);
- alfentanil (used in surgery for pain relief and to help anaesthesia);
- buspirone, alprazolam, brotizolam (used to treat anxiety or help you sleep);
- bosentan (used to treat pulmonary artery hypertension);
- gefitinib (used to treat breast, lung and other cancers);
- imatinib (used to treat lung cancer);
- oxybutynin (used to treat urinary incontinence);

- sildenafil (used to treat erectile dysfunction or pulmonary hypertension);
- axitinib, dabrafenib and ibrutinib (used to treat certain cancers);
- darifenacin (used to treat urinary incontinence);
- tolvaptan (used to treat low blood sodium levels);
- ebastine (used to treat allergies);
- reboxetine (used to treat depression);
- atorvastatin (used to lower cholesterol);
- eletriptan (used to treat migraine);
- fentanyl, a strong medicine for pain;
- riociguat (used to treat pulmonary hypertension);
- medicines taken for diabetes (in particular repaglinide);
- halofantrine (used to treat malaria);
- medicines which neutralize stomach acid or suppress the production of stomach acid (such as antacids, cimetidine, ranitidine, omeprazole).

TAKING ITRANOX CAPSULES

How much to use

Adults

The usual doses are shown below, but your doctor may decide to adjust them for your individual needs.

Tinea of body & groin:

1 capsule (100 mg) daily for 2 weeks.

Tinea of hands & feet:

1 capsule (100 mg) daily for 4 weeks.

Other skin infections:

2 capsules (200 mg) daily for 1 week.

Eye infections:

2 capsules (200 mg) daily for 3 weeks.

Vaginal infections:

2 capsules (200 mg) morning & evening for 1 day, or 2 capsules (200 mg) daily for 3 days.

Mouth infections:

1 capsule (100 mg) daily for 4 weeks or 2 capsules (200 mg) daily for 4 weeks.

Systemic infections:

1 to 2 capsules (100 mg to 200 mg) once or twice daily for 3 weeks to 8 months, depending on the condition.

Nail infections:

Continuous nail therapy

2 capsules (200 mg) once daily for 3 months.

Cyclic (pulse) nail therapy

2 capsules twice daily for 1 week. After that, stop taking ITRANOX for 3 weeks. Then the cycle is repeated, once for fingernails and twice for toenail infections (with or without fingernail infections). (See below).

Fingernails only

Week 1: Take 2 capsules twice daily.

Week 2, 3, 4: No ITRANOX.

Week 5: Take 2 capsules twice daily.

Week 6: Stop.

Toenails with or without fingernails

Week 1: Take 2 capsules twice daily.

Week 2, 3, 4: No ITRANOX.

Week 5: Take 2 capsules twice daily.

Week 6, 7, 8: No ITRANOX.

Week 9: Take 2 capsules twice daily.

Week 10: Stop.

Children and Elderly

ITRANOX capsules are not recommended for use in children and in the elderly.

How to take it

Always take ITRANOX capsules after a meal.

Do not take medicines that neutralise stomach acid within 2 hours of taking ITRANOX capsules. This is because sufficient stomach acid is required to ensure that ITRANOX capsule is properly absorbed by the body. If you take medicines that suppress the production of stomach acid, you should take your ITRANOX capsules with an acidic drink, such as a cola beverage.

If you forget to use 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 one 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 use too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (13 11 26) for advice, or go to Accident and Emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

WHILE YOU ARE USING ITRANOX

Things you must do

- Always follow your doctor's instructions carefully.
- If you have to take ITRANOX capsules continuously for more than 1 month, your doctor may ask you 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 ITRANOX, you should continue using adequate contraception until you have had your next period. Tell your doctor immediately if you do become pregnant while taking ITRANOX.
- If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking ITRANOX capsules.
- 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 ITRANOX capsules 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.

SIDE EFFECTS

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical

treatment if you get some side effects. Do not be alarmed by this list of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you experience any of the following:

- upset stomach, stomach pain or discomfort, nausea, vomiting, diarrhoea, constipation, an unpleasant taste in your mouth.
- shortness of breath, headache, dizziness, fever.
- a change in menstrual pattern.
- unusual hair loss or thinning.
- erectile dysfunction.
- muscle weakness or pain, painful joints.
- Inflammation of the pancreas.

Tell your doctor immediately if you notice any of the following as you may need urgent medical care:

- tingling, numbness or weakness in the hands or feet.
- swelling of hands ankles, feet, legs or abdomen.
- shortness of breath, unexpected weight gain, unusual fatigue, or begin to wake up at night. oversensitivity to sunlight.
- blurry or double vision, ringing in the ears.
- lose the ability to control your bladder or urinate much more than usual.

STOP taking ITRANOX capsules and tell your doctor immediately or go to Accident and Emergency at your nearest hospital if any of the following happen:

- abnormal tiredness, loss of appetite, nausea, vomiting, dark urine, pale stools, yellowing of the skin or eyes.
- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath or difficulty breathing, wheezing or trouble breathing.
- a severe skin disorder (widespread rashes with peeling skin and blisters in the mouth, eyes and genitals, or rashes with small pustules or blisters).
- you experience any hearing loss symptoms. In very rare cases, patients taking itraconazole have reported temporary or permanent hearing loss.
- Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

AFTER USING ITRANOX

Storage

Keep ITRANOX capsules in the pack until it is time to take them.

Keep ITRANOX capsules in a cool dry place where the temperature is below 25°C.

Keep your medicines where young children cannot reach them.

A locked cupboard at least one-and-a-half metres (1.5 m) above the ground is good place to store medicines.

Do not store ITRANOX capsules, or any other medicine, in the bathroom or near a sink. Do not leave medicines in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking ITRANOX capsules or your medicines has passed its expiry date, ask your pharmacist what to do with any medicine which may be left over.

PRODUCT DESCRIPTION

What it looks like

ITRANOX capsules are size “0e1” hard gelatin white opaque capsules filled with off-white to cream coloured pellets and imprinted with ‘ITR’ on cap and ‘100’ on body. They are supplied in a PVC/PE/PVDC/Aluminium blister packs of 15, 28 or 60 capsules.

Ingredients

The active ingredient in each ITRACONAZOLE GPPL capsule is 100 milligrams of itraconazole. Other ingredients include hypromellose, macrogol 20,000, sucrose and maize starch inside a hard gelatin capsule. The capsules are printed with TekPrint SW-9008 black ink.

SUPPLIER

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This leaflet was prepared: May 2016