

NEW ZEALAND CONSUMER MEDICINE INFORMATION

ITRAZOLE

Itraconazole capsule 100 mg



What is in this leaflet

This leaflet answers some common questions about Itrazole.

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 taking Itrazole against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What Itrazole is used for

Itrazole is 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;
- generalised infections.

Itrazole contains the active ingredient itraconazole. It belongs to a group of medicines called azoles.

It works by killing or stopping the growth of the fungus that causes the infection. Patches of skin may take a few weeks to completely clear up after you have finished

your treatment with Itrazole. Finger and toenails may take several months to completely clear up. This is because your skin or nail will only look normal after new skin or nail has grown, even though the medicine has killed the fungus that caused the infection.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

Before you take Itrazole

When you must not take it:

Do not take Itrazole if you have an allergy to:

- any medicine containing itraconazole
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take this medicine if you are pregnant or may become pregnant.

It may affect your developing baby if you take it during pregnancy. If there is any chance of you becoming pregnant, talk to your doctor about the need for highly effective contraception. Once you have finished taking Itrazole, you should continue using highly effective contraception until you have had your next period. Tell your doctor immediately if you do

become pregnant while taking Itrazole.

Do not give this medicine to a child.

Safety and effectiveness in children have not been established.

Do not take Itrazole if you have congestive heart failure (also called CHF) as Itrazole could make it worse.

If your doctor decides that you need to take Itrazole 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.

Do not take Itrazole with any of the following medicines:

- terfenadine, astemizole or mizolastine (used for allergy or hayfever);
- bepridil, felodipine, lercanidipine, ivabradine, ranolazine, eplerenone and nisoldipine (used to treat angina (crushing chest pain) or high blood pressure);
- domperidone (used to treat nausea and vomiting);
- ticagrelor (used for the prevention of heart attack or stroke);
- cisapride (used for certain digestive problems);
- certain medicines used to produce calmness or to help you sleep (midazolam (oral) or triazolam);
- simvastatin, lomitapide or lovastatin (used to lower your cholesterol);
- lurasidone, pimozide or sertindole (used to treat mental disorders);
- disopyramide, dronedarone, quinidine or dofetilide (used to treat irregular heartbeats);

- levacetylmethadol, methadone (used for severe pain or to manage opioid-dependency);
- dihydroergotamine and ergotamine (used to treat migraine);
- ergometrine or methylergometrine (used to control bleeding and maintain uterine contraction after child birth);
- halofantrine (used to treat malaria);
- irinotecan, an anti-cancer medicine;
- isavuconazole (used to treat fungal infections);
- naloxegol (used to treat constipation caused by taking opioid painkillers);
- avanafil (used to treat erectile dysfunction);
- dapoxetine (used to treat premature ejaculation);
- eliglustat (if you know you do not break down medicines that are broken down by the enzyme known as CYP2D6, you should check with your doctor if you can take this medicine).

If you have kidney or liver problems, do not take Itrazole capsules with any of the following:

- colchicine (used to treat gout);
- fesoterodine or solifenacin, when used to control irritated urinary bladder;
- telithromycin (an antibiotic).

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it:

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- liver problems
- kidney problems
- heart problems
- AIDS, or your immune system is not working as well as it should
- cystic fibrosis.
- allergic reactions to other antifungal medicines.
- you are an organ transplant patient.

Tell your doctor if you are breast-feeding or wish to breast-feed.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking Itrazole.

Taking other medicines

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

In particular, Itrazole must not be taken with some medicines.

Examples are:

- terfenadine, astemizole or mizolastine (used for allergy or hayfever);
- bepridil, felodipine, nisoldipine, lercanidipine, ivabradine, ranolazine, eplerenone (used to treat angina (crushing chest pain) or high blood pressure);
- cisapride (used for certain digestive problems);
- certain medicines used to produce calmness or to help you sleep (midazolam or triazolam);
- simvastatin, lomitapide or lovastatin (used to lower your cholesterol);
- lurasidone, pimozide or sertindole (used to treat mental disorders);
- disopyramide, dronedarone, quinidine or dofetilide (used to treat irregular heartbeats);
- levacetylmethadol, methadone (used to treat opioid-

dependency);

- ticagrelor (used for the prevention of heart attack or stroke);
- dihydroergotamine and ergotamine (used to treat migraine);
- ergometrine or methylergometrine (used to control bleeding and maintain uterine contraction after child birth);
- halofantrine, (used to treat malaria);
- irinotecan, an anti-cancer medicine;
- domperidone (used to treat nausea and vomiting)
- isavuconazole (used to treat fungal infections);
- naloxegol (used to treat constipation caused by taking opioid painkillers);
- avanafil (used to treat erectile dysfunction);
- dapoxetine (used to treat premature ejaculation);
- eliglustat (if you know you do not break down medicines that are broken down by the enzyme known as CYP2D6, you should check with your doctor if you can take this medicine).

If you have kidney or liver problems, do not take Itrazole capsules with the following medicines:

- colchicine (used to treat gout);
- fesoterodine or solifenacin, when used to control irritated urinary bladder;
- telithromycin (an antibiotic).

Wait at least 2 weeks after stopping Itrazole capsules before taking any of these medicines.

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

Examples of these medicines are:

- medicines that can reduce the gastric acid levels in your stomach;
- *saccharomyces boulardii*, a medicine used to treat certain

- diarrhea;
- artemether/lumefantrine or quinine (used to treat malaria)
 - phenytoin, phenobarbital or carbamazepine (used to treat epilepsy);
 - rifampicin, rifabutin, isoniazid, bedaquiline or delamanid (used to treat tuberculosis);
 - certain medicines used to treat HIV/AIDS, such as cobicistat, boosted elvitegravir, efavirenz, indinavir, maraviroc, nevirapine, saquinavir and ritonavir, ritonavir-boosted darunavir, ritonavir-boosted fosamprenavir, tenofovir disoproxil fumerate (TDF);
 - certain antineoplastics such as axitinib, bosutinib, bortezomib, brentuximab vedotin, busulphan, cabozantinib, carbazitaxel, carbozanitinib, ceritinib, cobimetinib, crizotinib, dabrafenib, dasatinib, docetaxel, erlotinib, ibrutinib, idelalisib, ixabepilone, lapatinib, nilotinib, nintedanib, olaparib, panobinostat, pazopanib, ponatinib, regorafenib, ruxolitinib, sonidegib, trabectedin, trastuzumab emtansine, vandetanib, vinca alkaloids (used to treat certain cancers);
 - sunitinib (used to treat certain types cancer);
 - gefitinib (used to treat breast, lung and other cancers);
 - imatinib (used to treat lung cancer);
 - busulfan (anti-cancer medicine);
 - aliskiren, diltiazem (to treat hypertension);
 - bosentan, digoxin, nadolol, riociguat, and certain calcium channel blockers, other dihydropyridines and verapamil (used to treat heart or blood pressure problems);
 - vorapaxar (used to treat heart attacks or stroke);
 - atorvastatin (used to lower cholesterol);
 - anticoagulants such as apixaban, coumarins & coumarin-like medicines (e.g. warfarin), cilostazol, dabigatran, rivaroxaban (used to slow blood clotting);
 - dutasteride, alfuzosin, silodosin (used to treat Benign Prostatic enlargement);
 - sildenafil (used to treat erectile dysfunction or pulmonary hypertension);
 - tadalafil, udenafil, vardenafil (used to treat erectile dysfunction);
 - colchicine (used to treat gout);
 - conivaptan, tolvaptan (used to treat low blood sodium levels);
 - mozavaptan; to treat low blood sodium;
 - fentanyl, a strong medicine for pain;
 - alfentanil, buprenorphine, oxycodone, sufentanil (used in surgery for pain relief and to help anaesthesia);
 - meloxicam, to treat joint inflammation and pain;
 - salmeterol (to improve breathing)
 - darifenacin, fesoterodine, imidafenacin, oxybutynin, tolterodine (used to treat urinary incontinence);
 - tamsulosin (used to treat male urinary incontinence)
 - ciprofloxacin, clarithromycin, erythromycin, telithromycin (antibiotics);
 - methylprednisolone, budesonide, ciclesonide, fluticasone and dexamethasone (often used for conditions such as inflammations, asthma and allergies);
 - bilastine, ebastine, rupatadine (used to treat allergies);
 - everolimus (given after an organ transplant)
 - cyclosporin, rapamycin (also known as sirolimus), tacrolimus, temsirolimus (used to help prevent organ transplant rejection or to treat certain problems with the immune system);
 - trimetrexate (used to treat certain type of pneumonia);
 - buspirone, perospirone, ramelteon, midazolam IV, alprazolam, brotizolam (used to treat anxiety or help you sleep);
 - aripiprazole, cariprazine, haloperidol, quetiapine, risperidone; to treat psychosis;
 - medicines taken for diabetes (in particular repaglinide and saxagliptin);
 - aprepitant, netupitant (used for nausea and vomiting during cancer treatment)
 - praziquantel, (used to treat fluke and tapeworms);
 - some contraceptive pills (birth control pills), such as dienogest, ulipristal;
 - reboxetine, venlafaxine (used to treat depression or anxiety);
 - cinacalcet, to treat an over active parathyroid;
 - alitretinoin (oral formulation), to treat eczema;
 - eletriptan (used to treat migraine);
 - medicines which neutralize stomach acid or suppress the production of stomach acid (such as antacids, cimetidine, ranitidine, omeprazole)
 - loperamide (used to treat diarrhea);
 - lumacaftor/ ivacaftor (used to treat Cystic Fibrosis);
 - guanfacine (used to treat Attention Deficit Hyperactivity Disorder);
 - suvorexant, zopiclone (used to treat insomnia);
 - cabergoline (used to treat Parkinsons Disease);
 - cannabinoids (used to treat nausea and vomiting, weight loss for patients with immune system problems and muscle spasms in patients with Multiple Sclerosis)
 - galantamine (used to treat Alzheimer's disease)
 - medicines use to treat Hepatitis C, such as simeprevir, boosted asunaprevir, boceprevir, daclatasvir, telaprevir, vaniprevir, glecaprevir/pibrentasvir; elbasvir/grazoprevir; ombitasvir/paritaprevir/ritonavir (with or without dasabuvir) combinations.
- Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Itrazole

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Adults

Your doctor will tell you how many Itrazole capsules to take, and for how long.

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

Tinea of body and groin:

1 capsule (100 mg) once daily for 15 days; or 2 capsules (200 mg) once daily for 7 days.

Tinea of hands and feet:

2 capsules (200 mg) twice daily for 7 days or 1 capsule (100 mg) once daily for 30 days.

Other skin infections:

1 capsule (100 mg) twice daily or 2 capsules (200 mg) daily for 5 to 7 days.

Eye infections:

2 capsules (200 mg) once daily for 21 days.

Vaginal infections:

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

Mouth infections:

1 capsule (100 mg) once daily for 15 days.

Systemic infections:

1 to 2 capsules (100 mg to 200 mg) once or twice daily for 3 weeks to 12 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 (200 mg) twice daily for one week. After that, stop taking Itrazole for 3 weeks. Then the cycle is repeated, once for fingernails and

twice for toenail infections (with or without fingernail infections).

Fingernail infections only:

Week 1: Take 2 capsules twice daily.

Week 2, 3, 4: No Itrazole.

Week 5: Take 2 capsules twice daily.

Week 6: Stop.

Toenail infections with or without fingernail infections:

Week 1: Take 2 capsules twice daily.

Week 2, 3, 4: No Itrazole.

Week 5: Take 2 capsules twice daily.

Week 6, 7, 8: No Itrazole.

Week 9: Take 2 capsules twice daily.

Week 10: Stop.

Children and Elderly

Itrazole is not recommended for use in children or in the elderly.

How to take it

Swallow the capsules whole with a full glass of water.

When to take it

Always take Itrazole immediately after a meal. This helps your body to absorb the medicine properly.

If you need to take an antacid, take it at least one hour before or 2 hours after your dose of Itrazole. This is because there must be enough acid in your stomach to ensure that your body can absorb Itrazole. If you take medicines that suppress the production of stomach acid, you should take your Itrazole with an acidic drink, such as a non-diet cola beverage.

How long to take it

Continue taking your medicine for as long as your doctor has told you to.

If you forget to take it

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

Otherwise, take it as soon as you remember, and then go back to

taking your medicine as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

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

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Itrazole. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking Itrazole

Things you must do

Always follow your doctor's instructions carefully.

If you have to take Itrazole continuously for more than 1 month, your doctor may ask you to have your blood checked regularly. This is to ensure that your liver is not affected.

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

Before starting any other new medicine, tell your doctor and pharmacist that you are taking Itrazole.

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 Itrazole to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery.

Be careful driving or operating machinery until you know how Itrazole affects you.

This medicine may cause dizziness, light-headedness or impaired vision in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, dizziness, light-headedness or impaired vision may be worse.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Itrazole.

This medicine helps most people with fungal infections, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- upset stomach, abdominal pain or discomfort, nausea, vomiting, diarrhoea or constipation
 - an unpleasant taste in your mouth
 - headache, dizziness, .
 -
 - a change in menstrual pattern
 - unusual hair loss or thinning
 - erectile dysfunction
 - muscle weakness or pain, pain joint,
 - sleepiness or drowsiness
 - confusion
 - numbness or tingling sensation
 - loss of sensation
 - gas or wind
 - indigestion or heartburn
 - runny nose, sneezing, and stuffiness.
- hives on the skin, swelling of the face, lips, tongue or other parts of the body,
 - shortness of breath or difficulty breathing, wheezing
 - chest pain
 - a severe skin disorder (widespread rashes with peeling skin and blisters in the mouth, eyes and genitals, or rashes with small pustules or blisters).
 - any hearing loss symptoms.

Tell your doctor as soon as possible if you notice any of the following:

- fever
- cough, chills, cold or flu-like symptoms
- tingling, numbness or weakness in the hands and feet
- increased heart rate
- swelling of hands, ankles, feet, legs or abdomen
- unexpected weight gain
- shortness of breath, 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
- facial pain, runny nose and nasal congestion.

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- abnormal tiredness, loss of appetite, dark urine, pale stools, yellowing of the skin or eyes
- sudden signs of allergy such as rash, itching or

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Some of these side effects for example, changes in liver function, cholesterol level. change in electrolytes in blood, blood sugar level or blood pressure can only be found when your doctor does tests from time to time to check your progress.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After taking Itrazole

Storage

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

If you take the capsules out of the pack they may not keep well.

Keep your capsules in a cool dry place where the temperature stays below 25°C.

Do not store Itrazole or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking this medicine or the expiry

date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Itrazole are red opaque, hard gelatin capsules printed axially with "MYLAN" over "IE 100" in white ink on the cap and body. The capsules contain white to off-white coloured pellets.

Ingredients

Active ingredient(s):

Itrazole contains 100 mg of itraconazole as the active ingredient.

Inactive ingredient(s):

Each capsule also contains:

- sugar spheres,
- hypromellose,
- sorbitan stearate
- and hydrated silica colloidal.

The capsule shell consists of:

- titanium dioxide (E171),
- red iron oxide (E172)
- and gelatin.

The white printing ink S-1-7078 consists of:

- shellac,
- ethanol,
- titanium dioxide (E171),
- isopropyl alcohol,
- propylene glycol,
- n-butyl alcohol,
- ammonium hydroxide
- and simeticone.

This medicine contains sucrose. If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: 0800 579 811

Date of Information

09 July 2021

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