

# **APO-ITRACONAZOLE**

Itraconazole

---

## **Consumer Medicine Information**

**For a copy of a large print leaflet, Ph: 1800 195 055**

## **What is in this leaflet**

This leaflet answers some common questions about itraconazole. 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 itraconazole against the benefits it is expected to 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 this medicine is used for**

Itraconazole is used to treat certain fungal infections, such as:

- infections of the nails, skin, hands, feet or groin
- persistent candida (yeast) vaginal infections
- 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 a weakened immune system
- generalised infections

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

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

Your doctor may have prescribed itraconazole for another reason.

This medicine is not addictive.

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

Itraconazole is not recommended for use in children and in the elderly.

# **Before you use this medicine**

## **When you must not take it**

**Do not take itraconazole if you have an allergy to:**

- 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 itraconazole if you are also taking any of the following medicines:**

- terfenadine, astemizole or mizolastine, used for allergies
- bepridil, felodipine, lercanidipine, ivabradine, ranolazine, eplerenone and nisoldipine, used for chest pain (angina) or high blood pressure
- domperidone, used for nausea and vomiting
- ticagrelor, used to prevent heart attacks or strokes
- cisapride, used for certain digestive problems

- midazolam or triazolam, used to help you sleep or relax
- some medicines used to lower your cholesterol (e.g. simvastatin, lovastatin or lomitapide)
- lurasidone, pimozone or sertindole, used to treat mental disorders
- disopyramide, dronedarone, quinidine or dofetilide, used to treat irregular heart beats
- levacetylmethadol or methadone, used for severe pain or opioid-dependency
- dihydroergotamine and ergotamine, used to treat migraines
- ergometrine or methyl-ergometrine, used after child birth
- halofantrine, used to treat malaria
- irinotecan, an anti-cancer medicine
- isavuconazole, used for 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 have kidney or liver problems, do not take itraconazole capsules with any of the following:**

- colchicine, used to treat gout
- fesoterodine or solifenacin, used to control irritated urinary bladder
- telithromycin, an antibiotic

**Do not take this medicine if you have heart failure.**

Itraconazole can worsen heart failure. If you must take it, tell your doctor if you experience symptoms of worsening heart failure such as shortness of breath, weight gain, swelling of the legs or fatigue.

**Do not take this medicine if you are pregnant or plan to become pregnant.**

Itraconazole 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 itraconazole, you should continue using highly effective contraception until you have had your next period.

**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, food, preservatives or dyes.**

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

- liver or kidney problems
- heart problems
- weakened immune system, such as neutropenia, AIDS or organ transplantation
- cystic fibrosis

**Tell your doctor if you are breast feeding.**

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

**If you have not told your doctor about any of the above, tell them before you start taking this medicine.**

## **Taking other medicines**

**Tell your doctor or pharmacist if you are taking any other medicines, including any that you can get without a**

**prescription from a pharmacy, supermarket or health food shop.**

Itraconazole must not be taken with some medicines. These include:

- terfenadine, astemizole or mizolastine, used for allergies
- bepridil, felodipine, lercanidipine, ivabradine, ranolazine, eplerenone or nisoldipine, used for chest pain (angina) or high blood pressure
- domperidone, used for nausea and vomiting
- ticagrelor, used to prevent heart attacks or strokes
- cisapride, used for certain digestive problems
- midazolam or triazolam, used to help you sleep or relax
- certain medicines used to lower your cholesterol (e.g. simvastatin or lovastatin or lomitapide)
- lurasidone, pimozide or sertindole, used for mental disorders
- disopyramide, dronedarone, quinidine or dofetilide, used for irregular heart beats
- levacetylmethadol and methadone, used for severe pain or opioid-dependency
- dihydroergotamine and ergotamine, used for migraines

- ergometrine or methylergometrine, used after child birth
- artemether-lumefantrine, halofantrine or quinine, used to treat malaria
- irinotecan, an anti-cancer medicine
- isavuconazole, used to treat fungal infections
- domperidone, used for nausea and vomiting
- naloxegol, used to treat constipation caused by taking opioid painkillers
- avanafil, used to treat erectile dysfunction
- dapoxetine, used to treat premature ejaculation
- eliglustat

**Medicines that must never be taken while you are taking itraconazole if you have kidney or liver problems:**

- colchicine, used to treat gout
- fesoterodine or solifenacin, used to control irritated urinary bladder
- telithromycin, an antibiotic

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

Certain medicines may interfere with itraconazole and how well it works. Your doctor may need to adjust the dose or adapt your treatment. These medicines include:

- anticoagulants such as apixaban, coumarins and coumarin-like medicines such as warfarin, cilostazol, dabigatran and rivaroxaban used to slow blood clotting
- some medicines used to treat hepatitis C (e.g. simeprevir, telaprevir, boosted asunaprevir, boceprevir, daclatasvir, vaniprevir, glecaprevir/pibrentasvir, elbasvir/grazoprevir, ombitasvir/paritaprevir/ritonavir (with or without dasabuvir) combinations)
- certain antibiotics (e.g. rifampicin, rifabutin, isoniazid, delamanid, bedaquiline, clarithromycin, erythromycin, ciprofloxacin, telithromycin)
- some medicines used to treat fits (e.g. phenytoin, phenobarbital or carbamazepine)
- certain medicines used to treat AIDS (e.g. cobicistat, elvitegravir, efavirenz, maraviroc, nevirapine, indinavir, saquinavir and ritonavir, ritonavir-boosted darunavir, ritonavir-boosted fosamprenavir, tenofovir disoproxil fumarate)
- some medicines used to treat heart and blood pressure problems (e.g. calcium channel blockers including amlodipine, nimodipine, nifedipine, other dihydropyridines and verapamil; digoxin, bosentan, nadolol or riociguat)

- aliskiren and diltiazem, used to treat hypertension
- vorapaxar, used to treat heart attacks or strokes
- atorvastatin, used to lower cholesterol
- some medicines used to treat immune system problems (e.g. cyclosporin, sirolimus, tacrolimus, temsirolimus, everolimus)
- darifenacin, fesoterodine, imidafenacin, oxybutynin, tolterodine, used to treat urinary incontinence
- tamsulosin, used to treat male urinary incontinence
- meloxicam to treat joint inflammation and pain
- some oral contraceptive pills (e.g. dienogest or ulipristal)
- corticosteroids (e.g. methylprednisolone, budesonide, ciclesonide, fluticasone or dexamethasone)
- trimetrexate, used to treat certain type of pneumonia
- some medicines used for pain relief and anaesthesia (e.g. alfentanil, fentanyl, buprenorphine, oxycodone or sufentanil)
- some medicines used for mood disorders (e.g. buspirone, alprazolam, brotizolam, reboxetine or venlafaxine)
- buspirone, perospirone, ramelteon, midazolam IV, alprazolam and brotizolam, used to treat anxiety or help you sleep

- aripiprazole, cariprazine, haloperidol, quetiapine or risperidone, used to treat psychosis
- alfuzosin, dutasteride or soldosin, used to treat benign prostatic enlargement
- sildenafil, used to treat erectile dysfunction or pulmonary hypertension
- tadalafil, udenafil or vardenafil, used to treat erectile dysfunction
- colchicine, used to treat gout
- certain antineoplastics such as bosutinib, bortezomib, brentuximab vedotin, carbazitaxel, cabozantinib, ceritinib, cobimetinib, crizotinib, dasatinib, erlotinib, idelalisib, ixabepilone, lapatinib, nilotinib, nintedanib, olaparib, panobinostat, pazopanib, ponatinib, regorafenib, ruxolitinib, sonidegib, trabectedin, trastuzumab emtansine, vandetanib, axitinib, dabrafenib and ibrutinib, busulphan, vinca alkaloids or docetaxel)
- sunitinib, used to treat certain types of bowel, stomach, or oesophagus tumours and kidney or pancreatic cancer
- gefitinib, used to treat breast, lung and other cancers
- imatinib, used to treat lung cancer
- tamsuconivaptan, tolvaptan or mozavaptan, used to treat low blood sodium levels
- bilastine, rupatadine or ebastine, used to treat allergies

- eletriptan, used to treat migraine
- repaglinide or saxagliptin, used for diabetes
- halofantrine, used to treat malaria
- medicines that suppress the production of stomach acid or antacids (e.g. cimetidine, ranitidine or omeprazole)
- salmeterol, used to improve breathing
- aprepitant or netupitant, used for nausea and vomiting during cancer treatment
- praziquantel, used to treat fluke and tapeworms
- cinacalcet, used to treat an over active parathyroid
- alitretinoin (oral formulation), used to treat eczema
- eletriptan, used to treat migraine
- *Saccharomyces boulardii* or loperamide, used to treat diarrhoea
- lumacaftor/ivacaftor, used to treat cystic fibrosis
- guanfacine, used to treat attention-deficit hyperactivity disorder (ADHD)
- suvorexant or zopiclone, used to treat insomnia
- cabergoline, used to treat Parkinson's disease
- galantamine, used to treat Alzheimer's disease

- cannabinoids, used to treat nausea and vomiting, weight loss for patients with immune system problems and muscle spasms in patients with multiple sclerosis

These medicines may be affected by itraconazole or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

**Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.**

## **How to take this medicine**

**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**

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) twice a day for 1 day, or 2 capsules (200 mg) daily for 3 days.

**Mouth infections:**

1 to 2 capsules (100 mg to 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****Fingernails only**

Week 1: Take 2 capsules twice daily.

Week 2, 3, 4: Do not take itraconazole.

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: Do not take itraconazole.

Week 5: Take 2 capsules twice daily.

Week 6, 7, 8: Do not take itraconazole.

Week 9: Take 2 capsules twice daily.

Week 10: Stop.

### **How to take it**

**Swallow the capsules whole with a glass of water.**

### **When to take it**

**Take your medicine at about the same time each day after a meal.**

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

**If you need to take an antacid, take it at least 2 hours before or 2 hours after your dose of this medicine.**

This is because sufficient stomach acid is required to ensure that itraconazole is properly absorbed by the body. If you take antacids, take itraconazole with an acidic drink such as a cola beverage.

## **How long to take it for**

**Continue taking your medicine for as long as your doctor tells you, even if the signs of infection have gone.**

## **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.**

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

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

## **If you take too much (overdose)**

**Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much of**

**this medicine. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

## **While you are using this medicine**

### **Things you must do**

**If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking itraconazole.**

**Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.**

**If you must take itraconazole continuously for more than one month, you may need regular blood checks to make sure that your liver is not affected.**

**If you become pregnant while taking itraconazole, tell your doctor immediately.**

**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 itraconazole, you should continue using highly effective contraception until you have had your next period.

## **Things you must not do**

**Do not take itraconazole to treat any other complaints unless your doctor tells you to.**

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

**Do not stop taking your medicine or lower the dosage without checking with your doctor.**

## **Side effects**

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

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 treatment if you get some 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, stomach pain or discomfort, nausea, vomiting, diarrhoea, constipation
- unpleasant taste in your mouth.
- shortness of breath
- headache, dizziness
- fever
- cough, chills, cold or flu-like symptoms
- a change in menstrual pattern
- unusual hair loss or thinning
- erectile dysfunction
- muscle weakness, pain, joint pain

The above list includes the more common side effects of your medicine.

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

- inflammation of the pancreas
- tingling, numbness or weakness in the hands or feet
- increased heart rate
- swelling of hands, ankles, feet, legs or abdomen, shortness of breath, weight gain, fatigue, night-time waking

- oversensitivity to sunlight
- blurry or double vision, ringing in the ears, hearing loss (may be temporary or permanent)
- losing control of your bladder or urinating much more than usual

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

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

- fatigue, loss of appetite, nausea, vomiting, dark urine, pale stools, yellowing of the skin or eyes (signs of a liver problem)
- 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 (signs of severe allergy)
- widespread rashes with peeling skin and blisters in the mouth, eyes and genitals, or rashes with small pustules or blisters (signs of Stevens-Johnson syndrome)
- hearing loss symptoms – in very rare cases, temporary or permanent hearing loss has been reported.

**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.

## **Storage and Disposal**

### **Storage**

**Keep the 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 itraconazole in a cool dry place where the temperature stays below 25°C.**

**Do not store itraconazole 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.

**Keep your medicines where young children cannot reach them.**

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

### **Disposal**

**If your doctor tells you to stop taking itraconazole 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

Size "0el" hard gelatin white opaque capsules filled with off-white to cream coloured pellets and imprinted with 'ITR' on cap and '100' on body with TekPrint SW-9008 black ink.

Available in a PVC/PE/PVDC/ Aluminium blister packs of 4, 6, 15, 28 or 60 capsules. AUST R 244473

### Ingredients

This medicine contains 100 mg of itraconazole as the active ingredient. This medicine also contains the following:

- hypromellose
- macrogol 20000
- sucrose
- maize starch
- gelatin
- TekPrint SW-9008 Black Ink.

This medicine does not contain lactose, gluten, tartrazine or any other azo dyes.

### Sponsor

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park NSW 2113

Australia

Tel: (02) 8877 8333

Web: [www1.apotex.com/au](http://www1.apotex.com/au)

This leaflet was prepared in July 2019.