

# ITRACAP

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I using ITRACAP?

ITRACAP contains the active ingredient itraconazole. ITRACAP 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 in patients with lower resistance to disease; generalised infections. For more information, see Section [1. Why am I using ITRACAP?](#) in the full CMI.

### 2. What should I know before I use ITRACAP?

Do not take if you have ever had an allergic reaction to ITRACAP or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are**

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**breastfeeding.** For more information, see Section [2. What should I know before I use ITRACAP?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with ITRACAP and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use ITRACAP?

Only take as many ITRACAP capsules as you have been prescribed and ask your doctor or pharmacist if you are not sure. More instructions can be found in Section [4. How do I use ITRACAP?](#) in the full CMI.

### 5. What should I know while using ITRACAP?

<b>Things you should do</b>	
	<ul style="list-style-type: none"><li>● Remind any doctor, dentist or pharmacist you visit that you are taking ITRACAP.</li><li>● Complete the treatment as directed by your doctor, even if the signs of infection have gone.</li><li>● Call your doctor straight away if you become</li></ul>

	pregnant while taking this medicine.
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not take ITRACAP to treat any other complaint unless your doctor says so.</li> <li>• Do not give this medicine to anyone else, even if their symptoms are similar to yours.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Be careful before you drive or use any machines or tools until you know how ITRACAP affects you.</li> <li>• ITRACAP may cause dizziness in some people.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Keep ITRACAP Capsules in a cool dry place where the temperature is below 25°C.</li> </ul>

For more information, see Section [5. What should I know while using ITRACAP?](#) in the full CMI.

## 6. Are there any side effects?

Common side effects include: stomach upset/pain/discomfort, nausea, vomiting, diarrhoea, constipation, unpleasant taste in mouth, shortness of breath, headache, dizziness, fever, change in menstrual pattern, hair loss/thinning, erectile dysfunction, muscle weakness/pain, painful joints, tremors, confusion, cough, chills, high or low blood pressure. Serious side effects include: tingling/numbness/weakness in hands/feet, swelling of hands/ankles/feet/legs/abdomen, shortness of breath, weight gain, tiredness/fatigue/beginning to wake up at night, oversensitivity to sunlight, blurry/double vision, ringing in ears, loss of ability to control bladder/urinating more, loss of appetite, nausea, vomiting, dark urine, pale stools, yellowing of skin/eyes, sudden signs of allergy (rash/itching/hives on skin, swelling of the face/lips/tongue/other parts of the body, shortness of breath/trouble breathing), severe skin disorder (widespread skin rashes/peeling and blisters in mouth/eyes/genitals), any hearing loss symptoms. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# ITRACAP Capsules

**Active ingredient(s):** *Itraconazole*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using ITRACAP capsules. 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 ITRACAP against the benefits this medicine is expected to have for you.

**You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ITRACAP.**

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

### Where to find information in this leaflet:

- [1. Why am I using ITRACAP?](#)
- [2. What should I know before I use ITRACAP?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ITRACAP?](#)
- [5. What should I know while using ITRACAP?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## **1. Why am I using ITRACAP?**

**ITRACAP contains the active ingredient itraconazole.**

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

**ITRACAP 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 in patients with lower resistance to disease;**
- **generalised infections.**

## **2. What should I know before I use ITRACAP?**

### **Warnings**

**Do not use ITRACAP if:**

- **you are allergic to itraconazole, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can take this medicine.**

- you have a condition called heart failure (also called congestive heart failure or CHF), ITRACAP could make it worse.
- you are pregnant or may become pregnant.

**Do not take ITRACAP with any of the following medicines:**

- certain medicines for allergy or hay fever (e.g. terfenadine, astemizole, mizolastine);
- certain medicines used to treat angina and high blood pressure (e.g. bepridil, felodipine, nisoldipine, lercanidipine, ranolazine, eplerenone) and ivabradine, a heart rate lowering agent;
- anticoagulants (used to slow blood clotting), such as apixaban, rivaroxaban, dabigatran;
- cisapride, a drug used to treat gastric reflux;
- domperidone, an antiemetic used to treat nausea, vomiting, bloating and fullness;
- levomethadyl and methadone, which are opioids;
- antipsychotic medications, such as pimozide, lurasidone and sertindole;
- ticagrelor, an anticoagulant;
- halofantrine, a medicine used to treat malaria;
- isavuconazole, an antifungal medicine;
- naloxegol, a medicine used to reduce opioid constipation;
- avanafil, a drug used for erectile dysfunction and dapoxetine, used for premature ejaculation;
- eliglustat, used to treat Gaucher disease;
- irinotecan, mobocertinib (used to treat cancer);

- venetoclax (used to treat certain cancers) in patients just starting or adjusting the dose of venetoclax;
- certain medicines used to produce calmness or to help you sleep (midazolam oral or triazolam);
- certain medicines used to lower your cholesterol, known as HMG-CoA reductase inhibitors, (e.g. simvastatin, lomitapide, lovastatin);
- dronedarone, dofetilide, quinidine or disopyramide (used to treat irregular heartbeats);
- dihydroergotamine or ergotamine (used to treat migraine);
- fesoterodine and solifenacin in patients with moderate to severe liver or kidney disease (these are medicines used to treat overactive bladder);
- colchicine in patients with severe liver or kidney disease (medicine used to treat gout and Behcet's disease);
- telithromycin in patients with severe liver or kidney disease (an antibiotic used to treat pneumonia);
- ergometrine or methylergometrine (used to control bleeding);
- finerenone (used to treat kidney problems in patients with type II diabetes);
- voclosporin (used to treat lupus-related kidney problems).

**Check with your doctor if you:**

- have or have had any other medical conditions, in particular:
- liver or kidney problems;



- allergic reaction to other medicines used to treat fungal infections;
- heart problems;
- neutropenia (low levels of a type of white blood cells) or AIDS or an organ transplant patient;
- hearing problems;
- weakness, numbness and pain from nerve damage, usually in the hands and feet;
- cystic fibrosis.
- take any medicines for any other condition;
- you have allergies to any other medicines, foods, preservatives or dyes.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

If there is a chance you may become pregnant, talk to your doctor about the need for highly effective contraception. Once you have finished ITRACAP, contraception should be continued until you have had your next period. Tell your doctor immediately, if you do become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Your doctor can discuss with you the risks and benefits involved.

### **3. What if I am taking other medicines?**

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

**In particular, ITRACAP must not be taken with some medicines. Wait at least 2 weeks after stopping ITRACAP before taking any of these medicines. Examples are provided in section 2. Do not take ITRACAP with any of the following medicines”.**

**Some medicines may be affected by ITRACAP or may interfere with ITRACAP and affect how it works.** Your doctor may need to adjust the dose or adapt your treatment.

**Examples of these medicines are:**

- alfuzosin, tamsulosin, silodosin (used to treat Benign Prostatic enlargement);
- alfentanil, buprenorphine, oxycodone, sufentanil (used in surgery for pain relief and to help anaesthesia);
- fentanyl, a strong medicine for pain;
- digoxin (used to treat heart failure);
- bedaquiline, delamanid, rifampicin, rifabutin or isoniazid (used to treat tuberculosis);
- trimetrexate, used to treat a certain type of pneumonia;
- anticoagulants (used to slow blood clotting), such as, edoxaban, vorapaxar, coumarins and coumarin like

medicines (e.g. warfarin); phenytoin, phenobarbital or carbamazepine (used to treat fits);

- medicines taken for diabetes, such as repaglinide and saxagliptin;
- praziquantel, a worm medication;
- artemether-lumefantrine, quinine (used to treat malaria);
- bilastine, ebastine, rupatadine (used to treat allergies);
- eletriptan (used to treat migraine);
- certain antineoplastics such as axitinib, bosutinib, bortezomib, brentuximab vedotin, busulfan, cabazitaxel, cabozantinib, ceritinib, cobimetinib, crizotinib, dabrafenib, dasatinib, docetaxel, erlotinib, entrectinib, gefitinib, glasdegib, imatinib, ibrutinib, idelalisib, ixabepilone, lapatinib, nilotinib, nintedanib, olaparib, panobinostat, pazopanib, pemigatinib, ponatinib, regorafenib, ruxolitinib, sonidegib, sunitinib, talazoparib, trabectedin, trastuzumab emtansine, tretinoin (oral), vandetanib, vinca alkaloids (used to treat certain cancers);
- alprazolam, aripiprazole, brotizolam, buspirone, cariprazine, haloperidol, midazolam i.v., perospirone, quetiapine, ramelteon, risperidone, suvorexant, zopiclone, (used to treat anxiety or help you sleep);
- certain medicines used to treat AIDS, such as cobicistat, darunavir (boosted), efavirenz, elvitegravir (boosted), fosamprenavir (ritonavirboosted), indinavir, maraviroc, nevirapine, saquinavir, tenofovir disoproxil fumarate, or ritonavir;
- boosted asunaprevir, boceprevir, daclatasvir, elbasvir/grazoprevir, glecaprevir/pibrentasvir, ombitasvir/

paritaprevir/ritonavir (with or without dasabuvir),  
vaniprevir (used to treat hepatitis C);

- aliskiren, bosentan, nadolol or riociguat (used to treat heart or blood pressure problems or hypertension);
- sildenafil or tadalafil (used to treat erectile dysfunction or pulmonary hypertension);
- certain calcium channel blockers (used to treat heart or blood pressure problems), such as diltiazem, verapamil or other dihydropyridines;
- contraceptives such as, dienogest or ulipristal;
- aprepitant, netupitant (used for nausea and vomiting during cancer treatment);
- *Saccharomyces boulardii*, loperamide (used to treat diarrhoea);
- budesonide, ciclesonide, cyclosporin, dexamethasone, fluticasone, methylprednisolone, sirolimus, tacrolimus, temsirolimus or everolimus (used to help prevent organ transplant rejection or to treat certain problems with the immune system);
- atorvastatin (used to lower cholesterol);
- meloxicam (a non-steroidal anti-inflammatory drug);
- salmeterol, a respiratory drug;
- reboxetine or venlafaxine (used to treat depression);
- darifenacin, vardenafil, dutasteride, imidafenacin, oxybutynin, tolterodine or udenafil (used to treat urinary disorders);
- cinacalcet, to treat an over active parathyroid;
- alitretinoin (oral formulation), to treat eczema;
- cabergoline (used to treat Parkinson'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);
- galantamine (used to treat Alzheimer's disease);
- ivacaftor, lumacaftor/ivacaftor (used to treat Cystic Fibrosis);
- guanfacine (used to treat attention deficit hyperactivity disorder and high blood pressure);
- conivaptan, tolvaptan, mozavaptan (used to treat low blood sodium levels);
- medicines used to reduce stomach acid such as antacids, H2 antagonists (e.g. ranitidine) proton pump inhibitors (e.g. omeprazole).

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ITRACAP.**

## **4. How do I use ITRACAP?**

### **How much to take**

#### **Adults**

ITRACAP is specially designed to give higher blood levels of active ingredient than other formulations of itraconazole capsules. A 50 mg capsule of ITRACAP is therapeutically equivalent to 100 mg of other brands of itraconazole capsules but the capsules are not interchangeable.

Only take as many ITRACAP capsules as you have been prescribed and ask your doctor or pharmacist if you are not sure.

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

**Tinea of body & groin:**

1 capsule daily for 2 weeks.

**Tinea of hands & feet:**

1 capsule daily for 4 weeks.

**Other skin infections:**

2 capsules daily for 1 week.

**Eye infections:**

2 capsules daily for 3 weeks.

**Vaginal infections:**

2 capsules morning & evening for 1 day, or 2 capsules daily for 3 days.

**Mouth infections:**

1 to 2 capsules daily for 4 weeks.

**Systemic infections:**

1 to 2 capsules once or twice daily for 3 weeks to 8 months, depending on the condition.

**Nail infections:**

Continuous nail therapy: 2 capsules once daily for 3 months.

Cyclic (pulse) nail therapy: 2 capsules twice daily for 1 week. After that, stop taking ITRACAP for 3 weeks. Then the cycle is repeated, once for fingernails and twice for toenail infections (with or without fingernail infections).

**Follow the instructions provided when ITRACAP was prescribed, including the number of days it should be taken.**

Don't worry if you don't see an immediate improvement after your treatment.

- With skin infections, the marks or spots (lesions) typically disappear a few weeks after you finish the course. Although the medicine kills the fungus, the marks don't disappear until after new skin has grown.
- With nail infections, marks on the nail may take 6 to 9 months to disappear, because new nail needs to grow.

**Ask your doctor or pharmacist if you're not sure whether the treatment is working.**

### **Children and Elderly**

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

### **When to take / use ITRACAP**

**Always take ITRACAP after a meal.**

**The capsules must be swallowed whole.**

Do not take medicines that neutralise stomach acid within 2 hours of taking ITRACAP capsules. This is because sufficient stomach acid is required to ensure that ITRACAP capsule is properly absorbed by the body.

If you take medicine that suppress the production of stomach acid, you should take your ITRACAP capsules with an acidic drink, such as a cola beverage.

## **How to take ITRACAP?**

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

## **If you forget to use ITRACAP**

ITRACAP should be taken regularly at the same time each day.

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 dose 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 use too much ITRACAP**

If you think that you have used too much ITRACAP, you may need urgent medical attention.

### **You should immediately:**

- phone the Poisons Information Centre **(by calling 13 11 26)**, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while using ITRACAP?**

### **Things you should do**

**Always follow your doctor's instructions carefully.**

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

**Always complete the treatment as directed by your doctor, even if the signs of infection have gone.**

### **Call your doctor straight away if you:**

- become pregnant while taking this medicine.

If there is any chance of you becoming pregnant, talk to your doctor about the need for adequate contraception.

Remind any doctor, dentist or pharmacist you visit that you are taking ITRACAP.

## **Things you should not do**

- Do not take ITRACAP to treat any other complaints unless your doctor tells you to.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how ITRACAP affects you.**

ITRACAP may cause dizziness in some people.

If you experience this or similar effects, you should avoid driving and using machines.

Make sure you know how you react to ITRACAP before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or lightheaded.

## **Looking after your medicine**

- Keep ITRACAP Capsules in the original pack until it is time to take them.
- Keep ITRACAP Capsules in a cool dry place where the temperature is below 25°C.

Do not store ITRACAP, 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 children cannot reach them. A locked cupboard at least one-and-a-half metres (1.5 m) above the ground is a good place to store medicines.**

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about 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.**

## Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>● upset stomach, stomach pain or discomfort, nausea, vomiting, diarrhoea, constipation, an unpleasant taste in your mouth</li><li>● shortness of breath, headache, dizziness, fever, confusion, cough, chills.</li><li>● a change in menstrual pattern</li><li>● unusual hair loss or thinning</li><li>● erectile dysfunction</li><li>● muscle weakness or pain, painful joints, tremors</li><li>● high or low blood pressure</li></ul>	<p><b>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>● tingling, numbness or weakness in the hands or feet</li> <li>● swelling of hands, ankles, feet, legs or abdomen</li> <li>● shortness of breath, unexpected weight gain, unusual fatigue, or beginning to wake up at night</li> <li>● oversensitivity to sunlight</li> <li>● blurry or double vision, ringing in the ears</li> <li>● loss of ability to control your bladder or urinating much more than usual</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>
<ul style="list-style-type: none"> <li>● abnormal tiredness, loss of appetite, nausea, vomiting, dark urine, pale stools, yellowing of the skin or eyes</li> <li>● sudden signs of allergy such as rash, itching or hives on the skin,</li> </ul>	<p><b>STOP taking ITRACAP and call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>swelling of the face, lips, tongue or other parts of the body, shortness of breath or difficulty breathing, wheezing or trouble breathing</p> <ul style="list-style-type: none"> <li>● a severe skin disorder (widespread rashes with peeling skin and blisters in the mouth, eyes and genitals, or rashes with small pustules or blisters)</li> <li>● any hearing loss symptoms. In very rare cases, patients taking ITRACAP have reported temporary or permanent hearing loss</li> </ul>	<p><b>these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at

[www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is available with a doctor's prescription.

### What ITRACAP contains

<b>Active ingredient (main ingredient)</b>	itraconazole
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>● hypromellose</li><li>● macrogol 20,000</li><li>● sucrose</li><li>● maize starch</li><li>● gelatin</li><li>● TekPrint SW-9008 Black Ink</li><li>●</li></ul>
<b>Potential allergens</b>	The capsules contain sulfites and sugars.

**Do not take this medicine if you are allergic to any of these ingredients.**

## **What ITRACAP looks like**

ITRACAP capsules are a size "0el" hard gelatin white opaque capsules filled with off-white to cream coloured pellets and imprinting with 'ITR' on cap and '100' on body (AUST R 244472)

They are supplied in a PVC/PE/ PVDC/Al blister pack of 4, 6, 15, 28 and 60 capsules.

Not all pack sizes are available.

## **Who distributes ITRACAP**

### **Sponsor**

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel St

Cremorne VIC 3121

[www.arrotex.com.au](http://www.arrotex.com.au)

### **Distributor**

ITRACAP is distributed in Australia by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone 1800 274 276



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