

Itraconazole 100mg Capsules, Hard

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1 What Itraconazole capsules are and what they are used for

Itraconazole capsules are indicated for the treatment of fungal infections of the vagina, skin, mouth, eyes, nails and internal organs.

The active substance is itraconazole, a member of the following pharmaco-therapeutic class of drugs: Antimycotic for systemic use, triazole derivatives.

Itraconazole is very effective against a variety of infections caused by yeasts and fungi.

It has great affinity for highly keratinized tissues such as skin and nails, as well as for the vaginal wall lining.

Therapeutic levels of itraconazole remain in the skin for two to four weeks following the end of treatment, depending on its duration.

In vaginal tissue, itraconazole can be found for a period of two to three days, again depending on the duration of treatment.

2 Before you take

Do not take Itraconazole capsules if you:

- are **pregnant** (only your doctor is in a position to decide if you need this drug).
- suffer from **congestive heart failure**.
- are **hypersensitive** to the active ingredient or any of the other ingredients of the formulation.

Children:

Children should not be given itraconazole, except for exceptional situations as assessed by the doctor.

Take special care with Itraconazole capsules

Please inform your doctor if you:

- have any type of **liver disease**

The dose may have to be adjusted. Consult your doctor immediately if you show any of the following symptoms when taking itraconazole: lack of appetite, nausea, vomiting, tiredness, abdominal pain or very dark urine. If you are taking itraconazole continuously for periods in excess of one month your doctor may ask for regular blood tests. The purpose of these tests is to check for the appearance of very rare liver problems resulting from drug use.

- have any type of **kidney disease**.

The dose may have to be adjusted if you:

- have a **history of any reaction** to antifungal medication.
- have Acquired Immunodeficiency Syndrome (**AIDS**) or your immune system is not working as well as it should.

Taking other medicines

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Examples of drugs that should never be taken with itraconazole include:

- Certain allergy medications, especially terfenadine, astemizole and mizolastine
- Cisapride, a drug used to treat certain digestive problems
- Certain cholesterol lowering drugs such as, for example, atorvastatin, simvastatin and lovastatin
- Sleep inducing drugs midazolam and oral triazolam
- Pimozide and sertindole, drugs to treat psychotic conditions
- Cardiac arrhythmia drugs quinidine and dofetilide
- Medicines used to treat angina (crushing chest pain) and high blood pressure called bepridil and nisoldipine
- Medicines for migraine headaches called eletriptan, dihydroergotamine and ergotamine
- Ergometrine (ergonovine) and methyl-ergometrine (methylegonovine) - used after giving birth
- Levacetylmethadol - for treatment of drug abuse (opioid-dependency)

Certain drugs can drastically decrease the action of itraconazole.

This is particularly true of certain drugs used to treat epilepsy (carbamazepine, phenytoin and phenobarbital) and tuberculosis (rifampicin, rifabutin and isoniazid).

Inform your doctor if you are taking any of these drugs so that proper measures may be taken.

Examples of drug combinations that may require adjusting the dose of itraconazole or of the other drugs:

- Antibiotics clarithromycin and erythromycin
- Antineoplastic agents
- Certain drugs that act on the heart and blood vessels (digoxin, disopyramide and some calcium channel blockers)
- Certain drugs used to regulate blood circulation
- Methylprednisolone, an oral or injectable anti-inflammatory
- Cyclosporin A, tacrolimus and rapamycin, normally used following organ transplantation
- Certain HIV Protease inhibitors (ritonavir, indinavir, saquinavir)
- Carbamazepine, rapamycin, alfentanil, alprazolam
- Certain drugs used to treat cancer
- Certain anti-anxiety drugs, especially buspirone and alprazolam
- Halofantrine – used for malaria

Proper absorption of itraconazole by the human body requires an adequate level of acidity. Therefore, drugs that inhibit stomach acid must not be taken for a period of two hours preceding itraconazole. For the same reason, if you are taking medication to decrease the formation of stomach acids, take itraconazole with a cola drink.

Bear in mind that these instructions may also apply to medication you took before or may take after.

Pregnancy

Ask your doctor or pharmacist for advice before taking any medicine.

Do not take Itraconazole capsules if you are pregnant. Women of childbearing age who may become pregnant must use proper contraception to ensure they do not get pregnant while under treatment with itraconazole.

Contraception should be used through the first normal menstrual cycle following termination of itraconazole treatment, as the drug can remain in the system for some time.

Breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Inform your doctor if you are breast-feeding and are prescribed Itraconazole capsules, as small amounts of the drug may be present in milk.

Taking Itraconazole capsules with food and drink

For maximum drug absorption itraconazole should be taken immediately following a meal.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed.

Important information about one of the ingredients of Itraconazole capsules

This medicine contains the sugar **sucrose**. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3 How to take

Always take Itraconazole capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Method and route of administration

Itraconazole must be taken immediately following a meal for optimum absorption. Capsules should be swallowed with a small amount of water.

Frequency and duration of treatment

The number of capsules and the duration of treatment will depend on the fungus and on the location of infection. Your doctor will tell you exactly what dose to take.

The following table lists some of the more frequent dosages:

Type of infection	Capsules per day	Duration
Vaginal infections	2 capsules (200mg itraconazole) twice a day or 2 capsules (200mg itraconazole) once a day	1 day 3 days
	2 capsules (200mg itraconazole) once a day or 1 capsule (100mg itraconazole) once a day	7 days 2 weeks
Skin infections	2 capsules (200mg itraconazole) once a day or 1 capsule (100mg itraconazole) once a day	7 days 2 weeks
	If there is a thin layer of callus on the palms of the hands or soles of the feet, it may be necessary to take 2 capsules (200mg itraconazole) twice a day for 7 days or 1 capsule (100mg itraconazole) once a day for one month.	
Infections of the mouth	1 capsule (100mg itraconazole) once a day	2 weeks
Infections of the internal organs	Higher doses	Longer periods

For nail infections, depending on your specific requirements, your doctor may opt for continuous or pulse treatment:

Type of infection	Capsules per day	Duration
Continuous nail treatment	2 capsules (200mg itraconazole) once a day	3 months

Pulse nail treatment	Week 1	W 2	W 3	W 4	W 5	W 6	W 7	W 8	W 9	W 10
	Toenails with or without fingernail involvement	Take 2 capsules (200mg itraconazole) twice a day	No itraconazole			Take 2 capsules (200mg itraconazole) twice a day	No itraconazole			Take 2 capsules (200mg itraconazole) twice a day
Finger nails only	Take 2 capsules (200mg itraconazole) twice a day	No itraconazole			Take 2 capsules (200mg itraconazole) twice a day	Suspend treatment				

When you should expect the results

Drug effects are not immediate.

In skin infections, lesions normally disappear a few weeks after treatment is suspended. This is characteristic of fungus lesions as the drug will eliminate the fungus but the lesions will remain until new skin grows.

Nail lesions will disappear six to nine months after treatment, as the drug will eliminate the fungus but new nail growth takes several months.

Do not worry if you see no improvement during the treatment. The drug will remain in your nails for several months and is doing its job.

Suspend treatment as soon as your doctor tells you to, even if you see no visible signs of improvement.

For infections of internal organs higher doses and longer treatment times may be required.

Do not forget to take your medication.

Follow these instructions unless your doctor tells you otherwise. Your doctor will tell you how long you should take Itraconazole capsules.

Do not interrupt treatment before being advised to do so by your doctor or cure may not be complete.

If you take more Itraconazole capsules than you should

Immediately consult your doctor or pharmacist if you take more Itraconazole capsules than you should.

If you forget to take Itraconazole capsules

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

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4 Possible side effects

Like all medicines, Itraconazole capsules can cause side effects, although not everybody gets them.

The following side effects can occur:

Common (affects 1 to 10 users in 100):

- distortion or decrease of the sense of taste (dysgeusia)

Uncommon (affects 1 to 10 users in 1,000):

- inflammation of the liver (hepatitis), jaundice
- localised swelling (oedema)

Very rare (affects less than 1 user in 10,000):

- reduced number of white blood cells (leukopenia, neutropenia)
- reduced number of thrombocytes (thrombocytopenia)
- severe allergic reactions
- too less potassium in the blood (hypokalemia)
- increase of triglycerides (a type of fat) in your blood (hypertriglyceridemia)
- headache, dizziness
- pain, loss of sensation, and inability to control muscles
- visual disorders, including blurred or double vision (diplopia)
- ear buzzing (tinnitus)
- abdominal pain, vomiting, nausea, diarrhoea, uncomfortable fullness after meals (dyspepsia), constipation
- hepatic enzyme increased
- rash, itching (pruritus), severe skin diseases, hair loss, increased sensitivity to sunlight
- muscular weakness, muscular pain and joint pain
- frequent daytime urination, urinary incontinence
- menstrual disorders, erectile dysfunction

Not known (frequency cannot be estimated from the available data):

- allergic reactions
- numbness and tingling (paraesthesia), loss of sensitivity to pain or touch (hypoesthesia)
- loss of heart ability to pump blood efficiently (congestive heart failure)
- abnormal build up of fluid in the lungs, which leads to swelling (pulmonary oedema)
- hepatotoxicity, acute hepatic failure

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5 How to store

Keep out of the reach and sight of children.

Do not store above 25°C.

Do not use Itraconazole capsules after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Further information

What Itraconazole capsules contain

Itraconazole capsules is presented in the form of hard gelatin capsules containing micro-granules.

The active substance is itraconazole. Each capsule contains 100mg of itraconazole (I.N.N.).

The other ingredients are:

Capsule contents: sugar spheres (maize starch and sucrose), poloxamer 188 and hypromellose
Capsule shell: indigo carmine (E 132), quinoline yellow (E 104), titanium dioxide (E 171) and gelatin.

What Itraconazole capsules look like and contents of the pack

Itraconazole capsules are opaque green and are available in blister packs of 15

Marketing authorisation holder:

Actavis Group PTC ehf.
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Iceland

Manufacturer:

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