

1.6.3 PATIENT INFORMATION LEAFLET (PIL)

Brand Names: INTRAZ (Itraconazole Capsules 100 mg)

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 further questions, please 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.

In this leaflet:

1. What **INTRAZ** is and what they are used for
2. Before you take **INTRAZ**
3. How to take **INTRAZ**
4. Possible side effects
5. How to store **INTRAZ**
6. Further information

1. What is INTRAZ and what they are used for?

- Vulvovaginal candidiasis,
- Oral candidiasis
- Dermatophytoses caused by organisms susceptible to ITRACONAZOLE (Trichophyton spp., Microsporum spp., Epidermophyton floccosum) e.g. tinea pedis, tinea cruris, tinea corporis, tinea manuum,
- Pityriasis versicolor,
- Onychomycoses caused by dermatophytes and/or yeasts,
- Systemic candidiasis,
- Cryptococcal infections (including cryptococcal meningitis). In immunosuppressed patients suffering from cryptococcosis and in patients with cryptococcosis of the CNS ITRACONAZOLE is indicated only if the usually recommended initial therapy seems to be inappropriate or ineffective
- Histoplasmosis.
- Aspergillosis. ITRACONAZOLE can be used to treat patients suffering from invasive aspergillosis who were found to be refractory or intolerant to Amphotericin B
- Maintenance therapy in AIDS patients to prevent relapse of underlying fungal infection who were found to be refractory or intolerant to first-line systemic anti-fungal therapy is inappropriate or has proved ineffective.

Due to PK properties, orally administered ITRACONAZOLE (capsules) should not be used as the initial treatment in patients with severe life-threatening forms of systemic mycoses. Oral forms should be used as a continuation therapy, after initial treatment with i.v. ITRACONAZOLE.

Consideration should be given to official guidance regarding the appropriate use of antifungal agents.

2. Before you take INTRAZ

Do not take ITRACONAZOLE capsules if:

- You are allergic to ITRACONAZOLE or any of the other ingredients of this medicine.
- You are pregnant or could become pregnant unless your doctor has told you to Do not use this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before using ITRACONAZOLE capsules.

Warnings and precautions

Talk to your doctor or pharmacist before taking ITRACONAZOLE capsules if:

- you have ever had kidney problems. Your dose of ITRACONAZOLE capsules may have to be changed
- you have ever had liver problems such as yellow skin (jaundice). Your dose of ITRACONAZOLE capsules may have to be changed.

If after taking this medicine you have a severe lack of appetite, feel sick (nausea), are sick (vomiting), feel unusually tired, get stomach pain, muscle weakness, yellowing of the skin or whites of the eyes, unusually dark urine, pale stools or hair loss, stop taking ITRACONAZOLE capsules and tell your doctor straight away

- you have ever had a heart problem including heart failure (also called congestive heart failure or CHF). ITRACONAZOLE capsules could make it worse. If after taking this medicine you get any of the following: - shortness of breath - unexpected weight gain - swelling of your legs or tummy - feel unusually tired - wake up short of breath at night stop taking ITRACONAZOLE capsules and tell your doctor straight away. These may be signs of heart failure.

Children and the elderly:

ITRACONAZOLE capsules are not normally given to children or the elderly. However, your doctor may prescribe them in special cases.

Blood tests:

If your ITRACONAZOLE capsules course is for more than one month, your doctor may want to check your liver by testing your blood.

Other medicines and ITRACONAZOLE capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription or herbal medicines. In particular, do not take this medicine and tell your doctor if you are taking any of the following:

- Medicines for hay fever or allergy called terfenadine, astemizole or mizolastine
- Medicines to lower cholesterol called atorvastatin, lovastatin or simvastatin
- Medicines for an irregular heart beat called quinidine or 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
- Cisapride - for digestive problems
- Ergometrine (ergonovine) and methylergometrine (methylergonovine) - used after giving birth
- Levacetylmethadol - for treatment of drug abuse (opioid-dependency)
- Midazolam (by mouth) or triazolam - for anxiety or to help you sleep
- Pimozide and sertindole - for conditions affecting thoughts, feelings and behaviour

Do not start taking ITRACONAZOLE capsules and tell your doctor if you are taking any of the above.

3. How to take INTRAZ?

The dosage of ITRACONAZOLE prescribed to each patient will vary. Always follow your physician's instructions and/or the directions on the prescription drug label.

Paediatric population

ITRACONAZOLE should not be administered to children as there is limited clinical data describing the pediatric use of this drug.

Elderly patients

Not recommended

Patients with hepatic impairment

Limited data are available on the use of oral ITRACONAZOLE in patients with hepatic impairment. Caution should be exercised when this drug is administered in this patient population.

Patients with renal impairment

Limited data are available on the use of oral ITRACONAZOLE in patients with renal impairment. Caution should be exercised when this drug is administered in this patient population.

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

Capsules must be swallowed whole with a small amount of water.

Mode of Administration: For oral use only.

What if you miss a dose of INTRAZ?

If your physician has instructed or directed you to take ITRACONAZOLE medication in a regular schedule and you have missed a dose of this medicine, take it as soon as you remember. However, if it is almost time for your next dose, then skip the missed dose and go back to your regular dosing schedule. Do not double the doses unless otherwise directed.

What if you overdose on INTRAZ?

Any medication taken in excess can have serious consequences. If you suspect an overdose of Aceclofenac-Paracetamol, seek medical attention immediately.

4. Possible side effects

Adverse Drug Reactions: Blood and lymphatic system disorders

Leukopenia, Neutropenia, Thrombocytopenia

Immune system disorders: Hypersensitivity

Anaphylactic Reaction, Anaphylactoid Reaction, Angioneurotic Oedema, Serum Sickness

Metabolism and nutrition disorders

Hypokalemia; Hypertriglyceridemia

Nervous system disorders: Headache, Dizziness, Paraesthesia, Hypoaesthesia

5. How to store ITRACONAZOLE

- Keep out of the reach and sight of children.
- Store below 30°C. Protect from moisture.

- Do not use the medicine after the expiry date, which is stated on the carton after (EXP). 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 INTRAZ (ITRACONAZOLE Capsules 100 mg) contain active ingredients are ITRACONAZOLE BP.

The inactive ingredients in the Capsules are Non Pareil Seeds 20#24 IHS.

7. What INTRAZ (ITRACONAZOLE Capsules 100 mg) Capsules look like and contents of the pack

INTRAZ (ITRACONAZOLE Capsules 100 mg) are a Scarlet/ Scarlet coloured hard gelatin capsule size '0' unprinted containing off white spherical pellets.

1 Capsules in Alu /PVDC Blister & 4 such Blister in a carton = 1 x 4's = 4 Capsules.

8. Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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