PACKAGE LEAFLET: INFORMATION FOR THE USER

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Itraconazole 100 mg capsules, hard

Itraconazole

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Itraconazole is and what it is used for
2. What you need to know before you take Itraconazole
3. How to take Itraconazole
4. Possible side effects
5. How to store Itraconazole
6. Contents of the pack and other information

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1 What Itraconazole is and what it is used for

Itraconazole belongs to a group of medicines called antifungals.

Itraconazole is used in cases of:
- **Superficial fungal infections** if external treatment is not effective or not appropriate.
  These include fungal infections
  - of the skin
  - *Pityriasis versicolor.* This is a fungal infection of the skin where branny scales develop after scratching. The affected skin parts are paler or darker than normal skin.

- **Fungal infections of mucosa and/or inner organs** caused by certain types of fungi.

2 What you need to know before you take Itraconazole

Do not take Itraconazole
- if you are **allergic** to itraconazole or to any of the other ingredients of this medicine (listed in section 6).
- if you are **taking any of the following medicines:**
  - **astemizole, mizolastine, terfenadine,** medicines against allergies
  - **bepridil, felodpine, lercarnidipine, nisoldipine, ivabrandine** or **ranolazine** medicines against high blood pressure and/or narrowed heart vessels
  - **quinidine, disopyramide, dronedarone** or **dofetilide,** medicines against disorders in the heart rhythm
  - **cisapride,** a stomach and bowel agent
  - **levacetylmethadole** or **levomethadyl** and **methadone,** used for the therapy of opiate dependents
  - **pimozide, lurasidone** and **sertindole,** used in schizophrenia
  - certain medicines to lower cholesterol levels, such as **lovastatin** and **simvastatin**
  - **colchicine in patients with kidney or liver problems,** a medicine against gout
  - **eplerenone,** a diuretic
  - **triazolam,** a medicine against sleep disturbances
  - **midazolam** for oral intake, a medicine for sedation before examinations, or operations or in intensive care units
  - **dihydroergotamine,** used in case of low blood pressure or certain headaches
  - **ergometrine** or **ergonovine, methylergometrine** or **methylergonovine,** medicines staunching bleeding used after birth
  - **ergotamine** and **eletriptan,** medicines against migraine
  - **halofantrine,** a medicine against malaria
  - **irinotectan,** used to treat cancer

  Do not start taking Itraconazole and tell your doctor if you are taking any of the above. Also, upon completing your course of Itraconazole, do not take any of the medicines listed above for 2 weeks.
- in case of signs of **heart dysfunction** or **previous heart failure,** except for the treatment of life-threatening or serious fungal infections
- if you are **pregnant or could become pregnant** unless your doctor has told you to (see 'Pregnancy and breast-feeding' below)

Warnings and precautions
Talk to your doctor before taking Itraconazole if any of the following items applies to you:
- **Taking other medicines**
  See also section "Other medicines and Itraconazole"
- **Heart problems** or if you have had heart problems in your medical history. Immediately inform a doctor if shortness of breath, unexpected weight gain, swollen legs or swollen abdomen, unusual exhaustion occur or if an inability to stay asleep newly occurs
- **Lowered acid content in the stomach**
  In patients with too little gastric juice, in certain AIDS patients or in case of drug use to prevent the production of gastric acid, an acidic drink such as non-diet cola is recommended when taking Itraconazole (see also section "Other medicines and Itraconazole" below).
- **Increased liver enzymes** or **existing liver disease**
  Treatment may be started only if the expected benefit is higher than the risk of liver damage. In such cases, your doctor will monitor the liver enzymes and adjust the dose, if necessary. If after taking this medicine you have signs of liver damage (see section 4), stop taking Itraconazole and tell your doctor straight away.
- **Impaired kidney function**
  Your doctor will adjust the dose, if necessary
- **Suppressed defence system,** such as in case of a reduced number of white blood cells, AIDS or after organ transplantations
- **AIDS patients** who are treated because of inner fungal infections and who are at risk of relapse. The attending physician will check whether continuous therapy is necessary
- **Previous allergic reactions** to medicines for the therapy of fungal infections. Medicines the active substances of which end with "azole" are predominantly concerned
- **Women who may become pregnant need to use contraception** while taking Itraconazole (see section 'Pregnancy and breast-feeding' below).

Children and older patients
Itraconazole is not normally given to children or older patients. However, your doctor may prescribe it in special cases.

Other medicines and Itraconazole
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

- **Medicines listed further above under "Do not take Itraconazole".**
  Concomitant treatment with these medicines and Itraconazole must not be performed. Also, upon completing your course of Itraconazole do not take any of these medicines for 2 weeks
- **Concomitant use with Itraconazole is not recommended, unless your doctor feels it is necessary, when taking:**
  - medicines for the treatment of cancer called **dasatinib, nilotinib** and **trabectedin**
  - **aliskiren,** for high blood pressure
  - **colchicine,** for gout
  - **everolimus,** usually given after an organ transplant
  - **fentanyl,** a strong painkiller
  - **rivaroxaban,** a medicine to thin blood
  - **salmeterol,** for asthma and other breathing problems
  - **tamsulosin,** for urinary incontinence in men
  - **vardenafil,** a medicine to treat erectile dysfunction
  Also, upon completing your course of Itraconazole, do not take any of the medicines listed above for 2 weeks.
- **Do not take any of following medicines 2 weeks before and while you are taking Itraconazole unless your doctor tells you otherwise:**
  - **rifampicin, rifabutin,** medicines against tuberculosis and leprosy
  - **phenytoin,** a medicine against convulsive attacks and nerve-induced states of pain
  - **carbamazepine, phenobarbital** medicines against convulsive attacks and certain pain
  - **isoniazid,** a medicine against tuberculosis and leprosy
  - **efavirenz, nevirapine,** medicines to treat HIV infections
- **Tell your doctor before taking, or if you are already taking, any of the following medicines.**
  They may stop Itraconazole from working properly. Your doctor may need to alter the dose of Itraconazole or your other medicine:
  - strong painkillers called **alfentanil, buprenorphine** (by injection or under your tongue) and **oxycodone**
  - **medicines for indigestion, stomach ulcers or heartburn** can affect the stomach producing acid. There must be enough acid in your stomach to make sure that your body can use the medicine. For this reason you should wait at least an hour after taking one of these other medicines before taking Itraconazole or wait for two hours after taking Itraconazole before taking any of these other medicines. If you take medicines that stop the production of stomach acid, you should take Itraconazole with a drink of cola (not diet cola).
  - **alprazolam,** a medicine against states of excitation and anxiety
  - **brotizolam,** a medicine against sleep disturbances marked by difficulties in falling asleep and awakening too early
  - **buspirone,** a medicine against states of excitation and anxiety
  - **medicines used in the treatment of cancer** such as bortezomib, busulfan, docetaxel, erlotinib, ixabepilone, lapatinib, trimetrexate and vinca alkaloids.
  - **medicines for conditions affecting thoughts, feelings and behaviour** called aripiprazole, haloperidol, perospirone, quetiapine, ramelteon and risperidone
  - **medicines inhibiting blood coagulation,** such as phenprocoumon, warfarin, cilostazol and dabigatran
  - **medicines against HIV infection** such as ritonavir, darunavir, indinavir, fosamprenavir and saquinivir and maraviroc
  - **medicines against bacterial infections** called ciprofloxacin, clarithromycin or erythromycin
  - **medicines that act on the heart and blood vessels** called nadolol, digoxin and cilostazol
  - **verapamil, nifedipine** and similar medicines against high blood pressure
  - certain **cortisones** such as budesonide, dexamethasone, fluticasone and methylprednisolone, used against various inflammations
  - **medicines to suppress the defence system and to avoid rejection of transplanted organs** called ciclosporin, rapamycin, also known as sirolimus, tacrolimus, ciclesonide or temsirolimus
  - **medicines to treat an overactive bladder:** fesoterodine, imidafenacin, solifenacin or tolterodine
  - **alitretinoin (by mouth),** a medicine to treat eczema
  - **aprepitant** and **domperidone,** medicines to stop you feeling and being sick
  - **atorvastatin,** a medicine to lower cholesterol
  - **cinacalcet,** a medicine for an over active parathyroid gland
  - **ebastine,** a medicine against allergies and itching
  - **eletriptan,** a medicine to treat migraine headaches
  - **mozavaptan** or **tolvaptan,** medicines to treat low sodium blood levels
  - **praziquantel,** for treatment of worms
  - **reboxetine,** a medicine against depression
  - **repaglinide** or **saxagliptin,** medicines in case of diabetes
  - **meloxicam,** a medicine to reduce inflammation and pain
  - **midazolam, injected into the vein,** for sedation before examinations or operations
  - **sildenafil** and **tadalafil,** medicines to treat erectile dysfunction

Tell your doctor before taking, or if you are already taking any of the above. They may need to alter the dose of Itraconazole or your other medicine.

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Pregnancy and breast-feeding

- **Itraconazole must not be used during pregnancy,** with the exception of life-sustaining therapies of inner fungal infections if the potential benefit outweighs the risks.

  Experience regarding use during pregnancy is low; cases of malformations are known. Short-term therapies (in fungal infections of female genital organs) in the first three months of pregnancy did not lead to an increased risk of malformations.

  For women who may become pregnant: Use contraception while taking this medicine and until your next period after the end of treatment.

  Tell your doctor straight away if you become pregnant while taking this medicine.

- **Itraconazole may be taken during breast-feeding only after the doctor has allowed it.** Only very low quantities of itraconazole pass into breast milk.

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

Driving and using machines
Itraconazole may make you feel dizzy and you may experience visual disturbances or hearing loss. Do not drive or operate machinery if this applies to you.

Itraconazole contains the sugar sucrose (saccharose)
This medicine contains sucrose (saccharose). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Itraconazole.

3 How to take Itraconazole

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose and duration of treatment are:
Superficial fungal infections

- **of the skin**
  1 capsule once daily, for 2 weeks

- **of the palms and soles of the feet**
  1 capsule once daily, for 4 weeks

- ***Pityriasis versicolor***
  2 capsules once daily, for 7 days.

  The doctor can double the dose in case of suppressed defence system, such as in reduced number of white blood cells, AIDS and after organ transplantations.

Itraconazole remains in the skin considerably longer than in the blood. Optimal healing is therefore achieved in fungal infections of the skin 2-4 weeks after the end of therapy.

Fungal infections of mucosa and/or inner organs caused by:

- ***Aspergillus***
  2 capsules once daily, for 2 to 5 months

  If the fungi spread into adjacent tissues or the whole body, 2 capsules twice daily

- ***Candida***
  1-2 capsules once daily, for 3 weeks up to 7 months

  If the fungi spread into adjacent tissues or the whole body, 2 capsules twice daily

- ***Histoplasma***
  2 capsules once to twice daily, for 8 months.

Method of use
Please take the capsules without chewing with a glass of water directly after a meal, and if possible, always at the same time of the day.

Take the capsules in the morning and in the evening if your intake is twice daily.

If you take medicines that stop the production of stomach acid, you should take Itraconazole with a drink of non-diet cola (see section 2 “Other medicines and Itraconazole” above.

If you take more Itraconazole than you should
Please immediately consult your doctor in this case.

If you forget to take Itraconazole
Take the forgotten dose as soon as you remember unless it is nearly time for the next dose. Do not take a double dose if you have forgotten to take your previous dose.

If you stop taking Itraconazole
Terminate therapy or change the dosage only after explicit agreement of your doctor. Otherwise, the therapeutic success could be endangered.

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

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using Itraconazole and tell your doctor straight away if you notice or suspect any of the following. You may need urgent medical treatment. The frequency of these side effects is rare.

- severe **allergic reactions** with signs such as:
  - sudden difficulty in breathing, speaking and swallowing
  - rash, hives (also known as nettle rash or urticaria), severe irritation of your skin
  - swelling of the lips, tongue, face and neck
  - extreme dizziness or collapse
- severe or itchy **skin rash,** which may show blistering, peeling and pain in the eyes, mouth or genital organs (life-threatening toxic epidermal necrolysis, Stevens-Johnson syndrome, acute generalised exanthematous pustulosis, erythema multiforme, exfoliative dermatitis, leukocytoclastic vasculitis)
- **liver damage** with possible signs such as
  - loss of appetite
  - nausea, vomiting
  - unusual tiredness
  - abdominal pain
  - yellowing of your skin or whites of your eyes (jaundice)
  - unusually dark urine, pale stools or
  - hair loss

  Severe liver damage including some fatal cases of acute liver failure and inflammation of the liver (hepatitis) have been reported
- **heart failure** with signs such as:
  - shortness of breath
  - unexpected weight gain
  - swelling of legs or abdomen
  - feeling unusually tired
  - waking up short of breath at night
  - shortness of breath can also be a sign of fluid on the lungs
- **nerve disturbances** called peripheral neuropathy, which manifest themselves as sensation of numbness, furry sensation or tingling in arms and legs
- **inflammation of the pancreas** with signs such as severe upper stomach pain, often with nausea and vomiting.

Other side effects can occur with the following frequencies:

Common, affects 1 to 10 per 100 users
- abdominal pain
- feeling sick (nausea)
- headache.

Uncommon, affects 1 to 10 per 1,000 users
- allergic reactions of different severity
- sinusitis, runny nose, coughs and colds
- being sick (vomiting)
- diarrhoea
- constipation
- indigestion
- wind
- increase in liver function tests
- nettle rash (urticaria)
- itching
- problems with menstrual periods.

Rare, affects 1 to 10 per 10,000 users
- reduction in the number of white blood cells which may increase the risk of infections
- serum disease; this disease is a hypersensitivity reaction of the body to foreign substances
- elevated blood fat values of triglycerides
- disturbed taste sensation
- visual disturbances including blurred vision and double vision
- hearing loss (may be permanent)
- noises in the ear (tinnitus)
- difficulty breathing
- need to urinate (empty bladder) more often
- swelling due to fluid under the skin
- unusual hair loss or thinning
- red, itchy, flaking or peeling skin
- sensitivity of the skin to light
- erection disturbances in men

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme: www.mhra.gov.uk/yellowcard. By reporting side effects, you can help provide more information on the safety of this medicine.

5 How to store Itraconazole

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and outer carton. The expiry date refers to the last day of that month.

Storage conditions
Do not store above 30°C.

Store the blister in the outer carton in order to protect from light.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6 Contents of the pack and other information

What Itraconazole contains
The active substance is: itraconazole.

Each hard capsule contains 100 mg itraconazole.

The other ingredients are:
Gelatin, hypromellose, macrogol, sucrose, maize starch, titanium dioxide (E 171).

What Itraconazole looks like and contents of the pack
Hard gelatin capsules, size 0, filled with white to off white pellets.
Capsule cap: white, opaque. Capsule body: white, opaque.

Itraconazole 100 mg capsules are packed in PVC-Aluminium or PVC/PVDC-Aluminium blister. The blister strips are packed in a carton box.

Packs containing 4, 6, 7, 8, 14, 15, 18, 20, 28, 30, 60, 84, 90 or 100 capsules, hard.

Not all pack sizes may be marketed.

Marketing authorisation holder
Sandoz Ltd, Frimley Business Park, Frimley, Camberley, Surrey, GU16 7SR, UK.

Manufacturer
Salutas Pharma GmbH, Otto-Von-Guericke-Allee 1, 39179 Barleben, Germany.

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