

Package leaflet: information for the patient

Itraconazole Ascend 100 mg, hard capsules  
itraconazole

Read the entire 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.
- Do you have any further questions? Please contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? This also applies to side effects not mentioned in this leaflet. Then contact your doctor or pharmacist.

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1. What is Itraconazole Ascend and what is this medicine used for?

Itraconazole Ascend contains the active substance itraconazole. It is a medicine used for the treatment of many types of fungal infections.

This medicine is used for: Superficial fungal infections

Is an external treatment not working well? Then this medicine is intended for the treatment of the following fungal infections:

- Fungal diseases of the female genital organs (vulvovaginal candidiasis).
- Powdery scaling of the skin due to a fungus, a skin disease with yellow spots due to a fungus (pityriasis versicolor).
- Skin diseases of the feet, body, legs, or hands due to a fungus (tinea pedis, tinea corporis, tinea cruris, tinea manus) (called dermatomycoses).
- Fungal diseases of the mouth, thrush (oral candidiasis).
- Only in adults: Fungal infections of the fingernails and toenails (caused by dermatophytes and/or yeast), associated with onycholysis and/or hyperkeratosis (detachment of the nail with increased callus formation).
- Inflammation of the cornea of the eye due to a fungus (caused by *Aspergillus* spp., yeasts [*Candida*], *Fusarium* spp.) (mycotic keratitis).

Fungal infections of the mucous membranes and/or internal organs (systemic mycoses)

This medicine is intended for the treatment of fungal infections of the mucous membranes and/or internal organs (systemic mycoses), such as  
Candidiasis

## Aspergillosis

Non-meningeal cryptococcosis. This medicine is only used if standard treatments prove unsuitable or do not work well in:

- patients with a compromised immune system who have cryptococcosis
- all patients with cryptococcosis of the central nervous system.

Histoplasmosis, sporotrichosis, paracoccidioidomycosis, blastomycosis, and other systemic or tropical mycoses that are rare (e.g., chromomycosis).

This medicine is used for the treatment of fungal infections of the membrane around the brain (cryptococcal meningitis) in patients:

- who do not respond to treatment with amphotericin B/flu cytosine (these are other medicines used for the treatment of fungal infections)
  - or for whom amphotericin B/flu cytosine cannot be used due to kidney damage or who cannot tolerate these medicines for other reasons.
2. When should you not take this medicine or be extra careful with it?

When should you not use this medicine?

- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6 of this leaflet.
- You are pregnant, think you might be pregnant, or could become pregnant (see the section 'Pregnancy and breastfeeding').
- Are you a woman who can have children and could become pregnant? Then you must use an effective method to ensure you do not become pregnant. This is necessary to be sure you do not become pregnant while using this medicine. After you stop taking this medicine, it remains in your body for some time. Therefore, you must continue using an effective method to prevent pregnancy until you have your next period after stopping the treatment.
- You have symptoms indicating that your heart is functioning very poorly (a heart chamber is not working well, such as congestive heart failure). You have a history of poorly functioning heart (congestive heart failure). You may use this medicine in the case of treatment of life-threatening or other serious infections (see also the section 'When should you be extra careful with this medicine?').

Are you taking any other medicines? Then contact your doctor before taking Itraconazole Ascend.

- Do not use Itraconazole Ascend if you are taking any of the following medicines, or within 2 weeks after stopping treatment with Itraconazole Ascend:

Medicines used for the treatment of heart, blood, or circulatory problems

aliskiren, eplerenone, lercanidipine, or nisoldipine (for high blood pressure)

bepidil, ivabradine, or ranolazine (for chest pain and pressure (angina pectoris))

dabigatran or ticagrelor (for blood clots)

disopyramide, dofetilide, dronedarone, or quinidine (for irregular heart rhythm)

finerenone (for kidney problems in patients with type 2 diabetes)

lomitapide, lovastatin or simvastatin (for lowering cholesterol)

sildenafil (for high blood pressure in the arteries of the lungs) Medicines for the treatment of stomach complaints or constipation  
cisapride (for stomach complaints)  
domperidone (for nausea and vomiting)  
naloxegol (for constipation due to taking strong painkillers (opiates))

Medicines for the treatment of headaches, sleep problems or mental health issues

dihydroergotamine or ergotamine (ergot alkaloids used for migraine)  
midazolam (taken orally) or triazolam (to become calm and relaxed or as a sleep aid)  
lurasidone, pimozide, quetiapine or sertindole (for schizophrenia, bipolar disorder or other mental health issues)

Medicines for the treatment of urinary tract problems

darifenacin (for difficulty holding urine (urinary incontinence))  
fesoterodine or solifenacin (for an irritated bladder) when used in patients with certain kidney or liver problems

Medicines for the treatment of allergies

astemizole, mizolastine or terfenadine (for allergies)

Medicines for the treatment of erection and ejaculation problems

avanafil (for erectile dysfunction)  
dapoxetine (for premature ejaculation)  
vardenafil (for erectile dysfunction) when used in men over 75 years

Other medicines containing the following:

colchicine (for gout) when used in patients with kidney or liver problems  
ergometrine (ergonovine) or methylergometrine (methylergonovine), ergot alkaloids used after childbirth  
eliglustat (for Gaucher's disease) if used in patients who cannot break down certain medications in their body  
halofantrine (for malaria)  
irinotecan (for cancer)  
isavuconazole (for fungal infections)  
ombitasvir, paritaprevir, ritonavir with or without dasabuvir (for the treatment of hepatitis C (liver inflammation))  
venetoclax (for chronic lymphocytic leukemia) when you are just starting venetoclax or using higher doses at the beginning of treatment  
voclosporin (for the treatment of kidney problems associated with a disease where your immune system does not function properly (lupus))

Reminder: do not take the medications mentioned above during the 2 weeks after your last treatment with Itraconazole Ascend.

This is not a complete list. Are you using any of these medications or another medication? Or are you planning to do so soon? Then tell your doctor.

When should you be extra careful with this medication?

Contact your doctor or pharmacist before taking this medication.

Stop taking this medication and contact your doctor immediately if you experience any of the following symptoms of severe liver problems during your treatment:

- severe loss of appetite, nausea, vomiting, unusual tiredness, abdominal pain, unusually dark urine, or pale stools.

Inform your doctor immediately:

- If you experience an unusual sensation of tingling, numbness, or weakness in your hands or feet while using this medication.
- If you experience symptoms of hearing loss. In very rare cases, patients using this medication have reported being temporarily or permanently deaf.

Inform your doctor before using this medication if you have or have had:

- an allergic reaction to another antifungal medication.
- a heart problem, including heart failure (also known as congestive heart failure). This medication can worsen it. Has your doctor decided to give you this medication? Then you must receive information about the symptoms listed below and what to watch out for. Do you experience any of the following symptoms? Then stop with taking this medication and contact your doctor immediately. The following symptoms may be signs of heart failure:
  - being short of breath
  - unexpected weight gain
  - swelling of your legs or abdomen
  - being unusually tired
  - waking up at night due to being short of breath
- a liver problem such as yellow skin (jaundice). Your dose of Itraconazole Ascend may need to be adjusted. Your doctor should tell you what symptoms to watch for. These symptoms may include: loss of appetite, nausea, vomiting, unusual tiredness, abdominal pain, unusually dark urine. Do you need to take this medication for a month without breaks? Then your doctor may want to check your liver with blood tests. It may also be that you are not allowed to use certain medications.
- a kidney problem. Your dose of Itraconazole Ascend may need to be adjusted. It may also be that you are not allowed to use certain medications.
- if your immune system is not functioning properly, for example in neutropenia (too few white blood cells in your blood), AIDS, or after an organ transplant. The dose of Itraconazole Ascend should then be increased.
- if you are an AIDS patient and have a fungal disease of the organs (for example, sporotrichosis, blastomycosis, histoplasmosis, cryptococcosis [with and without meningitis]). Your doctor will determine if you need maintenance therapy.
- if you have too little stomach acid. This can prevent itraconazole from being properly absorbed. Patients who are also taking medications that make stomach acid less acidic (for example, aluminum hydroxide) should take those medications at least 1 hour

before or 2 hours after taking Itraconazole Ascend. In patients who have no hydrochloric acid in the gastric juice (achlorhydria), such as some AIDS patients and patients taking medications to suppress hydrochloric acid (H<sub>2</sub> antagonists, proton pump inhibitors), it is recommended that they take this medication with regular cola (not diet cola). Your doctor will determine if the dosage of Itraconazole Ascend needs to be increased.

Are you unsure if any of the situations above apply to you? Then contact your doctor or pharmacist before taking this medication.

Children and adolescents up to 18 years

To date, there is little experience with the use of itraconazole in children and adolescents up to 18 years. Therefore, this medication should only be used in children and adolescents up to 18 years when the doctor has carefully weighed the benefits and risks.

Are you taking any other medications?

Are you taking any other medications besides Itraconazole Ascend, have you done so recently, or are you planning to do so soon? Then tell your doctor or pharmacist. This also applies to medications you can buy without a prescription and herbal remedies.

Are you taking Itraconazole Ascend? Then there are certain medications you should not use at the same time. These medications are listed above under the title "When should you not use this medication?".

Certain medications are not advised for use with Itraconazole Ascend. Your doctor may decide that you should not use certain medications with Itraconazole Ascend, or within 2 weeks after stopping treatment with Itraconazole Ascend.

Examples of these medications include:

Medications for the treatment of heart, blood, or circulatory problems

- apixaban, edoxaban, rivaroxaban, or vorapaxar (for blood clots)
- atorvastatin (for lowering cholesterol)
- felodipine (for high blood pressure)
- riociguat or tadalafil (for high blood pressure in the lungs)

Medications for the treatment of epilepsy, headache, or mental health problems

- phenytoin, carbamazepine, or phenobarbital (medications for epilepsy)
- eletriptan (for migraine)
- St. John's wort (*Hypericum perforatum*) (an herbal remedy used for mental health problems)

Medications for the treatment of urinary problems

- tamsulosin (for difficulty holding urine (urinary incontinence) in men)
- tolterodine (for an irritated bladder)
- Medications for the treatment of cancer
  - axitinib, bosutinib, cabazitaxel, cabozantinib, ceritinib, cobimetinib, crizotinib, dabrafenib, dasatinib, docetaxel, entrectinib, glasdegib, ibrutinib, lapatinib, nilotinib, olaparib, pazopanib, regorafenib, sunitinib, talazoparib, trabectedin, trastuzumab-

emtansine, venetoclax (when you are on a stable dose of venetoclax for chronic lymphocytic leukemia, or at any time during the treatment of acute myeloid leukemia) or vinca alkaloids (e.g., vinflunine, vinorelbine)

Medications for the treatment of tuberculosis

bedaquiline, isoniazid, rifabutin, or rifampicin (for tuberculosis)

Medications for the treatment of human immunodeficiency virus (HIV) or hepatitis

efavirenz or nevirapine (for HIV/AIDS)

elbasvir/grazoprevir, tenofovir/afenamifumarate (TAF), tenofovir disoproxil fumarate (TDF) (for HIV or hepatitis)

Medicines used after an organ transplant

everolimus, rapamycin (also called sirolimus), temsirolimus

Medicines for the treatment of benign enlargement of the prostate

alfuzosin, silodosin

Medicines for the treatment of lung problems or allergies

ciclesonide (for inflammation, asthma, and allergies)

ebastine (for allergies)

salmeterol (for asthma or chronic obstructive pulmonary disease, COPD)

Medicines for the treatment of erection and ejaculation problems

tadalafil or vardenafil (if used in men aged 75 years and younger) (for erectile dysfunction)

Other medicines containing the following:

colchicine (for gout)

fentanyl (for pain)

lumacaftor/ivacaftor (for cystic fibrosis)

Reminder: do not take the above-mentioned medicines during the 2 weeks after your last treatment with Itraconazole Ascend.

This is not a complete list. Are you using any of these medicines or another medicine? Or are you planning to do so soon? Then tell your doctor.

Be careful if Itraconazole Ascend is used together with certain other medicines. You may have a higher chance of side effects, or the dose of Itraconazole Ascend or the dose of the other medicine may need to be adjusted. Examples of these medicines are:

Medicines for the treatment of heart, blood, or circulatory problems

bosentan (for high blood pressure in the lungs)

calcium channel blockers such as dihydropyridines, like amlodipine, isradipine, nifedipine, nimodipine or diltiazem (for high blood pressure)

or verapamil (for high blood pressure)

cilostazol (for circulation problems)

coumarins such as warfarin (for blood clots)

digoxin (for an arrhythmia with a rapid, irregular heartbeat (atrial fibrillation))  
nadolol (for high blood pressure in the lungs or a painful and pressing feeling in the chest (angina pectoris))

#### Medicines for the treatment of stomach problems or diarrhea

aprepitant or netupitant (for nausea and vomiting during cancer treatment)  
loperamide (for diarrhea)  
antacids such as aluminum, calcium, magnesium, or sodium bicarbonate;  
H<sub>2</sub>-receptor antagonists such as cimetidine, ranitidine, and proton pump inhibitors such as lansoprazole, omeprazole, rabeprazole (for the treatment of acid reflux problems)

#### Medicines for the treatment of sleep problems or mental health issues

alprazolam, brotizolam, buspirone or midazolam (when given by injection into a vein) (for anxiety or as a sleep aid)  
zopiclone (as a sleep aid)  
reboxetine or venlafaxine (for depression and anxiety)  
aripiprazole, cariprazine, haloperidol or risperidone (for schizophrenia, bipolar disorder or other mental health issues)  
galantamine (for Alzheimer's disease)  
guanfacine (for ADHD)

#### Medicines for the treatment of urinary problems

imidafenacin, fesoterodine, oxybutynin, solifenacin (for an irritated bladder)

#### Medicines for the treatment of cancer

bortezomib, brentuximab vedotin, busulfan, erlotinib, gefitinib, idelalisib, imatinib, nintedanib, panobinostat, pemigatinib, ponatinib, ruxolitinib, sonidegib or tretinoin (orally)

#### Medicines for the treatment of infections

ciprofloxacin, clarithromycin or erythromycin (for bacterial infections)  
delamanid (for tuberculosis)  
artemether-lumefantrine or quinine (for the treatment of malaria)  
praziquantel (for flatworms and tapeworms)

#### Medicines for the treatment of human immunodeficiency virus (HIV) or hepatitis

cobicistat, ritonavir-boosted elvitegravir, maraviroc, ritonavir-boosted darunavir, ritonavir-boosted fosamprenavir, indinavir, ritonavir-boosted saquinavir or saquinavir (for HIV)  
glecaprevir/pibrentasvir (for hepatitis)

#### Medicines used after an organ transplant

ciclosporin or tacrolimus

#### Medicines for the treatment of benign prostatic hyperplasia

dutasteride

#### Medicines for the treatment of lung problems, allergies or inflammations

bilastine or rupatadine (for allergies)  
methylprednisolone or dexamethasone (medicines given orally or by injection for asthma, allergies or inflammations)  
budesonide or fluticasone (for asthma, allergies)

Medicines for the treatment of erectile and ejaculation problems

sildenafil (for erectile problems)

Medicines for the treatment of pain

alfentanil, buprenorphine, oxycodone, or sufentanil (for pain)  
meloxicam (for inflammation and joint pain)

Other medicines containing the following:

alitretinoin (given orally) (for eczema)  
cabergoline (for Parkinson's disease)  
cannabis-based products, including medicines (such as for nausea and vomiting or in patients with multiple sclerosis where muscles move involuntarily and cause pain)  
cinacalcet (for an overactive thyroid)  
dienogest or ulipristal (agents that prevent pregnancy)  
eliglustat (for Gaucher's disease) when used in patients who cannot metabolize certain drugs in their body  
ivacaftor (for cystic fibrosis)  
methadone (for the treatment of drug addiction)  
repaglinide or saxagliptin (for diabetes)

This is not a complete list. Are you using any of these medicines or another medicine? Or are you planning to do so soon? Then inform your doctor.

What should you pay attention to with food and drink?

Always take this medicine immediately after a meal. This improves the medicine's effectiveness in your body. Patients without hydrochloric acid in their gastric juice (achlorhydria), certain AIDS patients, or patients using medicines that reduce stomach acid production (such as H<sub>2</sub> antagonists, proton pump inhibitors) should take this medicine with an acidic drink, such as regular cola (not diet cola).

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Contact your doctor or pharmacist before using this medicine.

- Are you pregnant? Then do not use this medicine. Unless your doctor advises you to use it. Are you able to have children and could you become pregnant? Then contact your doctor. You must use an effective method to ensure you do not become pregnant. This is necessary to be sure you do not become pregnant while using this medication.
- After you stop taking Itraconazole Ascend, the medication remains in your body for some time. Therefore, you must continue to use an effective method to ensure you do

not become pregnant until you have your period again after stopping the treatment. Ask your doctor for advice on which type of contraception to use.

- Do you become pregnant after starting treatment with Itraconazole Ascend? Then stop taking it immediately and contact your doctor.
- Are you using this medication? Then you should not breastfeed, as small amounts of the medication can pass into your milk. Does your doctor advise you to use this medication? Then your doctor may conduct extra checks during the use of this medication.

#### Driving ability and the use of machines

This medication may cause dizziness, blurred/double vision, or hearing loss. Do you experience these symptoms? Then you should not drive or operate machines.

#### Itraconazole Ascend contains sucrose

Has your doctor told you that you cannot tolerate some sugars? Then contact your doctor before taking this medication.

### 3. How do you take this medication?

Always take this medication exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

The recommended dosage is:

Superficial mycoses (of the skin, mucous membranes, eyes)		
Indication	Dosage	Duration of treatment
Fungal infections of the female genital organs (vulvovaginal candidiasis)	2 times per day 2 hard capsules (this corresponds to 400 400 itraconazole itraconazole per day)	1 day
Skin diseases of the body or the legs due to a fungus (tinea corporis, tinea cruris)	1 time per day 2 hard capsules (this corresponds to with 200 mg itraconazole per day) or 1 time per day 1 hard capsule (this corresponds to 100 100 mg itraconazole per day)	7 days  or 2 weeks
Skin diseases of the palms and soles caused by a fungus (tinea pedis, tinea manus)	2 times per day 2 hard capsules (this corresponds to with 400 mg itraconazole per day) or 1 time per day 1 hard capsule (this corresponds to with 100 mg itraconazole per day)	7 days  or 4 weeks
Powdery scaling of the skin due to a fungus (pityriasis versicolor)	1 time per day 2 hard capsules (this corresponds to with 200 mg itraconazole per day)	7 days

Fungal diseases of the mouth, thrush (oral candidiasis)	1 time per day 1 hard capsule (this corresponds with 100 mg itraconazole per day)	15 days
Inflammation of the cornea of the eye (mycotic keratitis)	1 time per day 2 hard capsules (this corresponds to 200 200 mg itraconazole per day)	3 weeks

Fungal infections of the nails	
Treatment with intervals (intake with interruption)	Dosage and treatment duration
	<p>Treatment with intermittent periods consists of the following dosage regimen: 2 hard capsules 2 times a day (equivalent to 400 mg itraconazole per day) for 1 week.</p> <p>Treatments with intermittent periods are always interrupted by an intermittent period of 3 weeks without intake (see attached table).</p> <p>Treatments with 2 intermittent periods are recommended for infections of fingernails and treatments with 3 intervals for toenail infections. The clinical reaction becomes visible when the nail after the end of the treatment begins to grow again.</p> <p>If especially the toenails affected are, is it possible that the ultimate success of the treatment is only achieved after another 3 months (without treatment). For the safety may the treatment for fungal diseases of the nails not longer than 3 months.</p> <p><u>Note:</u> To achieve a good result, the affected nail area must be removed in such a way that this as little as possible wounds causes (for example with a urea ointment) before the treatment starts.</p>

Location of the fungal infections of the nail	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9
Toenails with or without affected fingernails	Interim period 1	Interim period of one week without itraconazole			Interim period 2	Weeks without itraconazole			Interval period 3
Only fingernails	Interval period 1	Interval of one week without itraconazole			Interval period 2				
Uninterrupted treatment (intake without interruption)		Dosage				Duration of treatment			
		1 time per day 2 hard capsules (this				Usually 3 months (if only the fingernails			

	corresponds to 200 mg itraconazole per day)	are affected, a shorter treatment period may be sufficient).
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Itraconazole remains many longer present in the skin and the nails than in the blood. This achieves optimal healing 2-4 weeks after stopping itraconazole capsules for fungal infections of the an optimal healing is achieved 2-4 weeks after stopping the intake of itraconazole capsules for fungal infections of the 6-9 months 6-9 months nails. Fungal diseases

Fungal diseases of the mucous membranes and/or internal organs (mycoses in the whole body)			
Indication	Dosage	Duration of treatment <sup>1</sup>	Remarks
Aspergillosis	1 time per day 2 hard capsules (this corresponds to 200 200 itraconazole per day) 2-5	2-5 In case of a deep	within the body penetrating invasive 2 times per day (in the morning and 2 times per day (in the morning and 's evening) (corresponds to 400 mg itraconazole per day) Candidiasis
Candidiasis	100-200 mg itraconazole per day) itraconazole per day)	3 - - 7 In case of a deep	within the body penetrating invasive 2 times per day (in the morning and evening) 's evening) (corresponds to 400 mg itraconazole per day) Non-meningeal cryptococcosis
Once a day 2 hard capsules (this corresponds to	1 time per day 2 hard capsules (this corresponds to 200 itraconazole per day) 2	2 - - 1 Higher	doses up to 600 mg per day have also been used in clinical studies.
Fungal infections of the membrane around the brain	2 times per day ('s morning and evening) 2 hard capsules (this corresponds to 400 mg itraconazole per day)	8-10 weeks	Higher doses up to 600 mg per day have also been used in clinical studies.

(cryptococcal meningitis)			Maintenance therapy: see section 2.
Histoplasmosis	1 time per day 2 hard capsules up to 2 times per day (morning and evening) 2 hard capsules (this corresponds to 200-400 mg itraconazole per day)	8 months	
Blastomycosis	1 time per day 1 hard capsule up to 2 times per day (morning and evening) 2 hard capsules (this corresponds to 100-400 mg itraconazole per day)	6 months	
Lymphocutaneous sporotrichosis and cutaneous sporotrichosis	1 time per day 1 or 2 hard capsules (this corresponds to 100 or 200 mg itraconazole per day) (sharply demarcated lesions) or 2 times per day 2 hard capsules (this corresponds to 400 mg itraconazole per day) (large lesions)	3-6 months	
Paracoccidioidomycosis	1 time per day 1 hard capsule (this corresponds to 100 mg itraconazole per day)	6 months	There are no data available on how well itraconazole capsules work in the treatment of paracoccidioidomycosis in AIDS patients at the stated dose.
Chromomycosis	1 time per day 1 to 2 hard capsules (this corresponds to 100-200 mg itraconazole per day)	6 months	

<sup>1</sup> Your doctor will adjust the duration of treatment based on the success of the treatment.

How do you take this medicine?

- Always take the capsules immediately after a meal with sufficient liquid (1 glass of water). This makes the medicine work better in your body.
- Swallow the capsules whole (without chewing them).
- Your stomach must contain enough acid. The acid ensures that the medicine works better in your body. Medicines used for problems with digesting food in your body, stomach ulcers, or heartburn can affect the production of acid by the stomach. Therefore, you must wait 2 hours after taking Itraconazole Ascend before taking any of these other medicines. Are you using medicines that stop the production of stomach acid? Then you must take Itraconazole Ascend with cola.

Have you taken too much of this medicine?

Have you taken too much of this medicine? Then contact your doctor immediately or go directly to the emergency department of the nearest hospital.

There are no data available on overdose. In case of overdose, supportive measures should be applied. Itraconazole cannot be removed from the body with a rinse (hemodialysis). No specific countermeasures are known.

Have you forgotten to take this medicine?

- Have you forgotten to take your capsules? Then take them as soon as you remember. Is it almost time for the next capsules? Then skip the missed capsules.
- Do not take a double dose to make up for a forgotten dose.

If you stop taking this medicine

Do not stop the treatment without first contacting the doctor treating you. If you stop your treatment too quickly or interrupt your treatment, your fungal infection may return.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

#### 4. Possible side effects

Like any medicine, this medicine can also have side effects. Not everyone will experience them.

Do you notice any of the following situations? Or do you think one of these situations applies to you? Then stop using this medicine and contact your doctor immediately. You may need urgent medical treatment.

- sudden wheezing, difficulty breathing, swelling of the face, skin rash, itching (especially all over the body) or a severe skin disease (widespread skin rash with peeling skin and blisters in the mouth, eyes, and genitals, or rash with small pustules or blisters)
- great loss of appetite, nausea, vomiting, unusual tiredness, abdominal pain, unusually dark urine or pale stools. These may be symptoms of serious liver problems.

Do you suffer from any of the side effects below? Then contact your doctor immediately.

- symptoms resembling heart failure, such as shortness of breath, unexpected weight gain, swelling of the legs, unusual tiredness, frequently waking up at night.
- a tingling sensation, sensitivity to light, numbness or weakness in the arms/legs.
- blurred vision/double vision, ringing in the ears, difficulty holding urine or needing to urinate more often.
- symptoms of hearing loss.
- severe pain in the upper abdomen, often with nausea and vomiting due to inflammation of the pancreas (pancreatitis).

Do you suffer from any of the side effects below? Then contact your doctor or pharmacist.

Common (occur in less than 1 in 10 users):

- stomach pain
- nausea
- headache

Sometimes (occur in less than 1 in 100 users):

- inflammation of the nose, upper respiratory tract infection, sinusitis
- hypersensitivity
- diarrhea, vomiting, constipation, poor digestion, excessive flatulence
- your liver is not functioning properly
- hives, rash, itching
- abnormal bleeding during menstruation

Rare (occur in less than 1 in 1,000 users):

- certain blood disorders (leukopenia)
- serum sickness, painful swelling of the skin and mucous membranes (angioneurotic edema), hypersensitivity reactions (anaphylactic reaction)
- too many fats (triglycerides) in the blood
- tingling or weakness in your hands and feet (paresthesia), reduced sensitivity to pain (hypoesthesia), unpleasant taste in your mouth (dysgeusia)
- vision problems, including blurred vision and double vision
- temporary or permanent hearing loss, ringing in the ears (tinnitus)
- your heart is not functioning well. You may experience symptoms such as shortness of breath, unexpected weight gain, swelling of your legs or abdomen, unusual fatigue, frequent nighttime awakenings (congestive heart failure)
- difficulty breathing (dyspnea)
- severe upper abdominal pain, often with nausea and vomiting (pancreatitis)
- severe liver problems (hepatotoxicity, including sudden liver failure, which can be fatal), high bilirubin levels in the blood
- severe allergic skin reactions (such as toxic epidermal necrolysis, Stevens-Johnson syndrome, acute generalized exanthematous pustulosis, erythema multiforme,

- exfoliative dermatitis, or leukocytoclastic vasculitis) along with multiple skin changes, hair loss, sensitivity to light
- unusually frequent urination (pollakisuria)
- problems achieving an erection (erectile dysfunction)
- your body retains fluid (edema)
- high creatine phosphokinase levels in the blood

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

- symptoms of high levels of the hormone 'aldosterone' (such as high blood pressure or low potassium levels in the blood), even if the 'aldosterone' level in the blood is normal or low
- The following side effects have been reported in patients using other dosage forms containing itraconazole:
  - certain blood disorders (granulocytopenia, thrombocytopenia)
  - symptoms of hypersensitivity (anaphylactoid reaction)
  - high blood sugar levels
  - muscle cramps or irregular heartbeat (possible symptoms of high or low potassium levels in the blood)
  - muscle cramps or irregular heartbeat (possible symptoms of low magnesium levels in the blood)
  - being confused
  - nerve damage in the arms and legs, causing pain or numbness, burning and tingling sensation, dizziness, drowsiness, trembling
  - heart failure (when the heart pumps blood less effectively, along with shortness of breath, fatigue, and swelling of the ankles), rapid heartbeat (tachycardia)
  - high blood pressure, low blood pressure
  - fluid in the lungs, difficulty speaking, coughing
  - gastrointestinal disease
  - liver failure, inflammation of the liver (hepatitis), yellowing of the skin (jaundice)
  - skin rash with redness of the skin, excessive sweating
  - muscle pain (myalgia), joint pain (arthralgia)
  - kidney problems
  - difficulty holding urine (urinary incontinence)
  - general swelling, swelling of the face, chest pain, fever, pain, exhaustion, chills
  - unusual results of urine and blood tests, high values in certain liver function tests (elevated liver enzyme levels)

## Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet.

You can also report side effects via the Netherlands Pharmacovigilance Centre Lareb, website: [www.lareb.nl](http://www.lareb.nl).

By reporting side effects, you help us obtain more information about the safety of this medicine.

## 5. How to store this medicine?

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date. You can find this on the blister pack and the box after "EXP". It includes a month and a year. The last day of that month is the expiry date.
- Store below 30 °C.
- Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal of medicines ensures they are destroyed correctly and do not enter the environment.

6. Contents of the package and other information What substances are in this medicine?

- The active substance in this medicine is: itraconazole. Each hard capsule contains 100 mg itraconazole.
- The other substances in this medicine are:  
Contents of the capsule:  
Sugar spheres, hypromellose 2910, poloxamer 188, macrogol 20000, talc, and colloidal anhydrous silica

Capsule shell:

Gelatin, sodium lauryl sulfate, titanium dioxide (E171), patent blue V (E131), and carmoisine (E122)

Printing ink:

Shellac (E904), propylene glycol (E1520), ammonium hydroxide (E527), potassium hydroxide (E525), titanium dioxide (E171)

What does Itraconazole Ascend look like and what is in a package?

Itraconazole Ascend 100 mg hard capsules are white to off-white granules filled in a hard gelatin capsule with a blue, opaque cap and a pink transparent body of size "0", printed with white ink with "Itraconazole" on the cap and "100" on the body.

PVC/PCTFE blister packs Package sizes:

4, 6, 7, 8, 10, 14, 15, 18, 28, 30, 60, and 100 hard capsules.

It is possible that not all mentioned package sizes are marketed.

Marketing authorization holder and manufacturer

Ascend GmbH

c/o Pollux Business Center GmbH Sebastian-Kneipp-Straße 41 60439 Frankfurt am Main  
Germany

Manufacturer

Ascend GmbH

Sebastian-Kneipp-Straße 41 60439 Frankfurt am Main Germany

Registered under:

RVG 133677

This medicine is registered in member states of the European Economic Area under the following names:

Netherlands Itraconazole Ascend 100 mg, hard capsules

Germany Itraconazole Ascend 100 mg Hartkapseln

This leaflet was last approved in November 2025.

Transtoyou