

PACKAGE LEAFLET: INFORMATION FOR THE USER

Sporanox 10 mg/mL Oral Solution

(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 symptoms 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.

What is in this leaflet

- 1. What Sporanox oral solution is and what it is used for**
- 2. What you need to know before you use Sporanox oral solution**
- 3. How to use Sporanox oral solution**
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- 6. Contents of the pack and other information**

1. What Sporanox oral solution is and what it is used for

Sporanox is one of a group of medicines called “antifungals”. These medicines are used for infections caused by fungi – including yeasts. They can be used to treat these infections – or stop you from getting them.

You may be given Sporanox to:

- treat yeast infections of the mouth, throat or gullet – if you have a poor immune system
- stop you from getting some fungal infections – if you have a poor immune system due to a major blood problem or bone marrow transplantation.

2. What you need to know before you use Sporanox oral solution

Do not use Sporanox:

- If you are allergic (hypersensitive) to itraconazole or to any of the ingredients in this medicine (listed in Section 6)
- If you are pregnant, think you might be pregnant or could become pregnant (see the section on Pregnancy below)

Do not take Sporanox if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before having this medicine.

Medicines you must not take with Sporanox

Do not use Sporanox if you are taking certain medicines (also do not use within 2 weeks of stopping Sporanox).

Examples of these medicines are:

Medicines for the heart, blood or circulation problems

- aliskiren, eplerenone, lercanidipine or nisoldipine (for high blood pressure)
- bepridil, ivabradine or ranolazine (for angina – crushing chest pain)
- dabigatran or ticagrelor (for blood clots)
- disopyramide, dofetilide, dronedarone or quinidine (for uneven heart beat problems)
- finerenone (for kidney problems in patients with type 2 diabetes)
- lomitapide, lovastatin or simvastatin (to lower cholesterol)
- sildenafil when used to treat pulmonary hypertension (increased blood pressure in the blood vessels in the lungs)

Medicines for stomach problems or constipation

- cisapride (for stomach upsets)
- domperidone (for nausea and vomiting)
- naloxegol (for constipation caused by taking opioid painkillers)

Medicines for headaches, sleep or mental health problems

- dihydroergotamine or ergotamine (ergot alkaloids used for migraine headaches)
- midazolam (taken by mouth) or triazolam (for anxiety or to help you sleep)
- lurasidone, pimozide, quetiapine or sertindole (for schizophrenia, bipolar disorder or other mental health problems)

Medicines for problems passing water or bladder problems

- darifenacin (for when you lose control of your bladder)
- fesoterodine or solifenacin (for irritated bladder) when used in patients with certain kidney or liver problems

Medicines to treat allergies

- astemizole, mizolastine or terfenadine (anti-histamines for allergies)

Medicines for erection and ejaculation problems

- avanafil (for erectile dysfunction)
- dapoxetine (for premature ejaculation)
- vardenafil (for erectile dysfunction) when used in men older than 75 years of age

Other medicines containing:

- colchicine (for gout) when used in patients with kidney or liver problems
- ergometrine (ergonovine) or methylergometrine (methylergonovine) (ergot alkaloids used after giving birth)
- eliglustat (for Gaucher's disease) when used in patients that cannot break down certain medicines in the body
- halofantrine (for malaria)
- irinotecan (for cancer)
- isavuconazole (for fungal infections)
- ombitasvir, paritaprevir, ritonavir with or without dasabuvir – (to treat hepatitis C)
- venetoclax (for chronic lymphocytic leukaemia) when you newly start venetoclax or take increasing doses at beginning of treatment
- voclosporin (to treat lupus-related kidney problems)

Do not use Sporanox if any of the above apply to you. If you are not sure, talk to your doctor before using Sporanox. Also, when you have finished your course of Sporanox, do not take any of the medicines listed above for 2 weeks

This is not a complete list, so tell your doctor if you are taking or planning to take any of these medicines, or any other medicines.

Warnings and precautions

Look out for serious side effects

Stop taking Sporanox and tell your doctor straight away if while taking this medicine:

- you have severe loss of appetite, unusual tiredness, stomach pain, very dark urine or pale stools, or you feel or are sick – they may be signs of severe liver problems
- you have any unusual feelings of tingling, numbness or weakness in your hands or feet – or become sensitive to light
- you have any hearing loss – in very rare cases patients taking Sporanox have reported temporary or permanent hearing loss

Stop taking Sporanox and tell your doctor straight away if you have any of the above or are not sure.

Talk to your doctor

You must tell your doctor before taking Sporanox if you have ever had:

- an allergic reaction to any other antifungal medicines
- a heart problem, including heart failure – Sporanox could make it worse. Your doctor may tell you about the signs of heart failure to watch out for. If you get any of the following stop taking Sporanox *and* tell your doctor straight away. These may be signs of heart failure:
 - shortness of breath
 - unexpected weight gain
 - swelling of your legs or stomach
 - feel unusually tired
 - wake up short of breath at night
- any liver problem or, jaundice (yellowing of the skin) because your dose of Sporanox may have to be changed. Your doctor may tell you about symptoms to watch out for and ask you to have your blood checked. Also, you may not be able to take some medicines.
- a kidney problem – because your dose of Sporanox may have to be changed. Also, you may not be able to take some medicines.
- cystic fibrosis – an illness that runs in families and affects the lungs, pancreas, liver, kidneys and intestines.

Other medicines and Sporanox oral solution

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Medicines you must not take

There are some medicines that **you must not take** while taking Sporanox - these are listed above under the heading “**Medicines you must not take with Sporanox**”

Medicines that are not recommended

Your doctor may decide that you should not take some medicines at the same time as, or within 2 weeks of stopping Sporanox oral solution.

Examples of these medicines are:

Medicines for the heart, blood or circulation problems

- apixaban, edoxaban, rivaroxaban or vorapaxar (for blood clots)
- atorvastatin (to lower cholesterol)
- felodipine (for high blood pressure)
- riociguat or tadalafil when used to treat pulmonary hypertension (increased blood pressure in the blood vessels in the lungs)

Medicines for epilepsy, headaches or mental health problems

- phenytoin, carbamazepine or phenobarbital (for epilepsy)
- eletriptan (for migraine headaches)
- St. John’s Wort (*Hypericum perforatum*) (a herbal medicine used for mental health problems)

Medicines for problems passing water or bladder problems

- tamsulosin (for male urinary incontinence)
- tolterodine (for irritated bladder)

Medicines for 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 leukaemia, or at any time of treatment for acute myeloid leukaemia) or vinca alkaloids (such as vinflunine, vinorelbine)

Medicines for tuberculosis

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

Medicines for HIV or hepatitis

- efavirenz or nevirapine (for HIV/AIDS)
- elbasvir/grazoprevir, tenofovir alafenamide fumarate (TAF), tenofovir disoproxil fumarate (TDF) (for HIV or hepatitis)

Medicines for inflammation, lung problems or allergies

- ciclesonide (for inflammation, asthma and allergies)
- ebastine (for allergies)
- salmeterol (for asthma or chronic obstructive pulmonary disease -COPD)

Medicines for erection and ejaculation problems

- tadalafil or vardenafil (for erectile dysfunction) when used in men 75 years of age and younger

Other medicines containing:

- colchicine (for gout)
- fentanyl (for pain)
- everolimus, rapamycin (also known as sirolimus) or temsirolimus (given after an organ transplant)
- alfuzosin or silodosin (for benign prostatic enlargement)
- lumacaftor/ivacaftor (for cystic fibrosis)

Tell your doctor before taking Sporanox if you are taking any of the above medicines. Also, after finishing your course of Sporanox, you need to wait 2 weeks before taking these medicines. This is not a complete list, so tell your doctor if you are taking or planning to take any of these medicines, or any other medicines.

Medicines where the dose may need to be altered

Tell your doctor before taking certain medicines – as the dose of Sporanox or other treatments may need to be altered.

Examples of these medicines are:

Medicines for the heart, blood or circulation problems

- bosentan (for pulmonary hypertension)
- calcium channel blockers such as, dihydropyridines such as amlodipine, isradipine, nifedipine, nimodipine or diltiazem or verapamil (for high blood pressure)
- cilostazol (for circulatory problems)
- ‘coumarins’ such as warfarin (for blood clots)
- digoxin (for atrial fibrillation)
- nadolol (for pulmonary hypertension or angina)

Medicines for stomach problems or diarrhoea

- aprepitant or netupitant (for nausea and vomiting)
- loperamide (for diarrhoea)
- antacids such as aluminium, calcium, magnesium, or sodium bicarbonate; H₂-receptor antagonists such as cimetidine, ranitidine and proton pump inhibitors such as lansoprazole, omeprazole, rabeprazole (to treat stomach acid problems)

Medicines for sleep problems or mental health problems

- alprazolam, brotizolam, buspirone, or midazolam (when injected into a vein) (for anxiety or to help you sleep)
- zopiclone (to help you sleep)

- reboxetine or venlafaxine (for depression and anxiety)
- aripiprazole, cariprazine, haloperidol or risperidone (for schizophrenia, bipolar disorder or other mental health problems)
- galantamine (for Alzheimer's disease)
- guanfacine (for attention deficit hyperactivity disorder)

Medicines for problems passing water or bladder problems

- imidafenacin, fesoterodine, oxybutynin or solifenacin (for irritated bladder)

Medicines for cancer

- bortezomib, brentuximab vedotin busulfan, erlotinib, gefitinib, idelalisib, imatinib, nintedanib, panobinostat, pemigatinib, ponatinib, ruxolitinib, sonidegib or tretinoin (given by mouth)

Medicines to treat infections

- ciprofloxacin, clarithromycin, or erythromycin (for bacterial infections)
- delamanid (for tuberculosis)
- artemether-lumefantrine or quinine (to treat malaria)
- praziquantel (for fluke and tapeworms)

Medicines for HIV or hepatitis

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

Medicines for inflammation, lung problems, allergies

- bilastine or rupatadine (for allergies)
- methylprednisolone or dexamethasone, (medicines given by mouth or injection for inflammation, asthma and allergies)
- budesonide or fluticasone (for asthma and allergies)

Medicines for erection and ejaculation problems

- sildenafil (for erectile dysfunction)

Medicines for pain

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

Other medicines containing:

- cyclosporine or tacrolimus (given after an organ transplant)
- dutasteride (for benign prostatic enlargement)
- alitretinoin (given by mouth) (for eczema)
- cabergoline (for Parkinson's disease)
- cannabis based products including medicines (such as for nausea and vomiting or muscle spasms in patients with multiple sclerosis)
- cinacalcet (for an over active parathyroid)
- dienogest or ulipristal (contraceptives)
- eliglustat (for Gaucher's disease) when used in patients that cannot break down certain medicines in the body
- ivacaftor; (for cystic fibrosis)
- methadone (to treat drug addiction)
- repaglinide or saxagliptin (for diabetes)

Tell your doctor before taking any of the above medicines - as the dose of Sporanox or other treatments may need to be altered.

This is not a complete list, so tell your doctor if you are taking or planning to take any of these medicines, or any other medicines.

Sporanox oral solution with food and drink

Do not take Sporanox with food or drink as it reduces your body's ability to absorb the medicine.

- Always take Sporanox oral solution one hour before any food or drink as this helps the body absorb the medicine.

Children

Sporanox is not normally given to children. Your doctor may prescribe it in special cases.

Sporanox contains cyclodextrin, propylene glycol and alcohol (ethanol). Do not use in children less than 2 years old unless recommended by your doctor. If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if the child is given other medicines that contain cyclodextrin, propylene glycol or alcohol.

Elderly

Sporanox is not normally given to the elderly. Your doctor may prescribe it in special cases.

Pregnancy

Do not take Sporanox if you are pregnant, unless your doctor has told you to.

If you are of child bearing age and could become pregnant, talk to your doctor.

- Use effective contraceptives to make sure that you do not become pregnant while you are taking your medicine.
- Also, keep using some form of contraception until your next period after you have stopped SPORANOX. This is because Sporanox remains in the body for some time after you stop taking it.

If you do find that you are pregnant after starting a course of Sporanox, stop taking it and tell your doctor straight away.

Before taking any medicine - always tell your doctor if you are pregnant, think you might be pregnant or are trying to become pregnant.

Breast-feeding

If you are breast-feeding do not take Sporanox. This is because small amounts of the medicine could be present in your breast milk. If, your doctor recommends taking Sporanox they may carry out extra checks while you are taking this medicine.

Driving and using machines

Sporanox can sometimes cause dizziness, blurred or double vision or hearing loss. If this happens to you, do not drive or use machines or tools.

Sporanox oral solution contains sorbitol

This medicine contains 7 920 mg sorbitol in a 40 mL dose which is equivalent to 198 mg in each mL. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take this medicine. Sorbitol is a source of fructose and may cause gastrointestinal discomfort and mild laxative effect.

Sporanox oral solution contains propylene glycol

This medicine contains 4.2 g of propylene glycol in each 40 mL dose which is equivalent to 104 mg/mL. If you are pregnant, breast-feeding or suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

Sporanox oral solution contains cyclodextrin

This medicine contains 16 000 mg cyclodextrin (s) in each 40 mL which is equivalent to 400 mg/mL. Cyclodextrin may cause digestive problems such as diarrhoea.

Sporanox oral solution contains alcohol (ethanol)

This medicine contains 0.2 mg of alcohol (ethanol) in each 40 mL dose which is equivalent to 0.005 mg/mL. The amount in 40 mL of this medicine is equivalent to less than 1 mL beer or 1 mL wine. The small amount of alcohol in this medicine will not have any noticeable effects.

Sporanox oral solution contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 40 mL, that is to say essentially 'sodium-free'.

3. How to use Sporanox oral solution

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

When to take Sporanox

Always take Sporanox one hour before any food or drink – as this helps the body absorb the medicine.

How to take Sporanox

Swish the oral solution around in your mouth for about 20 seconds before swallowing it. Do not rinse your mouth after swallowing the oral solution.

How much to take

A measuring cup with a mark to show 10 mL is provided. Make sure you fill the cup to the 10 mL mark.

Yeast infections of the mouth, throat or gullet

- The usual dose is 2 measuring cups (20 mL) each day for one week.
- This may be taken either all at once or in two separate doses during the day.

If after one week, your infection has not cleared, your doctor may decide to continue treatment for one more week.

Already treated yeast infections of the mouth, throat or gullet – but have still not cleared

- The usual dose is 1-2 measuring cups (10-20 mL) twice daily for two weeks.
- This may be continued for an extra two weeks, if the infection does not clear in the first two weeks.
- Some patients are on the higher dose of 4 measuring cups a day. This should be limited to 14 days.

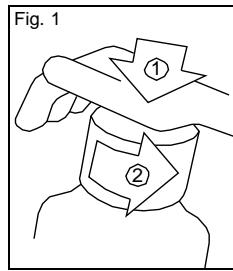
Prevention of fungal infections

The dose is worked out according to your body weight (5 mg for each kg). this is given in two separate doses each day. Your doctor will tell you exactly how much you should take.

How to open the bottle

The bottle comes with a child-proof cap – which you open like this:

1. push the plastic screw cap down
2. at the same time, turn it anti-clockwise.



How to use the measuring cup

Use the measuring cup just as it sits on the bottle.

- Make sure that the side with the markings (the side that holds less) is up that is the side you have to fill.
- When the arrow on the side points up, the correct side is up.

If you take too much Sporanox

If you, or anyone else, take more Sporanox than you were told to, contact your doctor or local hospital without delay.

If you forget to take Sporanox

If you forget to take your medicine, take the next dose as usual. Do not take a double dose.

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

4. Possible side effects

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

Serious side effects

Stop taking Sporanox and tell your doctor straight away if while taking this medicine:

- you have severe loss of appetite, unusual tiredness, stomach pain, very dark urine or pale stools, or you feel or are sick - these may be signs of severe liver problems.
- you have any unusual feelings of tingling, numbness or weakness in your hands or feet - or become sensitive to light.
- you have any hearing loss – in very rare cases patients taking Sporanox have reported temporary or permanent hearing loss.
- you have sudden breathing problems, swelling of the face, rash, itching (especially affecting the whole body) or severe skin problems (widespread rashes with peeling skin and blisters in the mouth, eyes and genitals, or rashes with small pustules or blisters) - these are signs of a serious allergic reaction.

Stop taking Sporanox and tell your doctor straight away if you have any of the above or are not sure.

Also tell your doctor straight away if you have any of the side effects below:

- Signs of heart failure – such as shortness of breath, unexpected weight gain, swelling of the legs, being unusually tired, repeated waking at night.
- Blurred vision or double vision, ringing in your ears, lose the ability to control your urine or increased need to pass water.
- Severe upper stomach pain, often feeling and being sick – due to inflammation of the pancreas.

Tell your doctor straight away if you have any of the above or are not sure.

Other side effects include:

Common side effects – may affect up to 1 in 10 people:

- Headache, fever or high temperature
- stomach ache, feeling sick (nausea), being sick (vomiting), diarrhoea, indigestion, unpleasant taste
- rash
- shortness of breath or cough
- dizziness

Uncommon side effects – may affect up to 1 in 100 people:

- certain blood problems which may increase the risk of bleeding or bruising or infections (possible symptom of low levels of white blood cells)
- constipation
- itching, hives, general swelling
- muscle cramps or uneven heart beat
- muscle pain, painful joints
- abnormal menstrual bleeding
- decreased feeling or sensitivity – especially in the skin

The following side effects have been reported in patients taking Sporanox but we do not know how often this happens:

- too many triglycerides (fats) in the blood
- hair loss
- increase in a blood test called “creatinine phosphokinase levels”
- symptoms of increased levels of the hormone ‘aldosterone’ (such as high blood pressure or low blood potassium levels), even though the ‘aldosterone’ blood level is normal or low
- decrease in heart rate

Side effects seen with other types of Sporanox medicines (tablets, injection)

The following side effects have been reported in patients taking other types of Sporanox:

- the common cold (infection of the upper respiratory tract)
- inflammation of the nose or sinuses
- fluid in the lungs
- blood problems which may increase the risk of infections
- high blood sugar levels
- muscle cramps, or uneven heart beat or chest pain
- confusion or difficulty speaking
- sleepiness, feeling very tired (fatigue)
- tremors, chills or too much sweating
- increase in heart rate
- high or low blood pressure
- too much gas in the gut
- inflammation of the liver and yellowing of the skin
- kidney problems or too much urine production
- erectile dysfunction
- facial or general swelling
- pain
- changes in test results such as increase in blood urea levels, abnormal urine findings or liver tests

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Sporanox oral solution

Keep out of the reach and sight of children.

Do not store this medicine oral solution above 25 °C.

Do not use this medicine oral solution after the expiry date printed on the packaging. The expiry date refers to the last day of that month.

The oral solution should not be used for longer than 1 month after the bottle has first been opened.

Always return any leftover medicine to your pharmacist. Only keep it if your doctor tells you to.

6. Contents of the pack and other information

What Sporanox oral solution contains:

- The active ingredient is itraconazole (10 mg of itraconazole per mL).
- The other ingredients are hydroxypropyl- β (cyclodextrin), sorbitol (liquid non crystallising) E 420, propylene glycol E 1520, hydrochloric acid, cherry flavour 1 and 2 (contains ethanol), caramel flavour, sodium saccharin, sodium hydroxide and water.

What Sporanox oral solution looks like and the contents of the pack:

Sporanox oral solution is a clear, yellow to slightly amber solution. It is available in bottles containing 150 mL together with a measuring cup.

Marketing Authorisation Holder:

Janssen Sciences Ireland UC,
Barnahely, Ringaskiddy, Co. Cork,
P43 FA46,
Ireland.

Manufacturer:

Sporanox oral solution is manufactured by:
Janssen Pharmaceutica NV,
Turnhoutseweg 30,
B-2340 Beerse,
Belgium.

This medicine is authorised in the member states of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Belgium: SPORANOX®

Ireland: SPORANOX®

Italy: SPORANOX®

Luxembourg: SPORANOX®

Portugal: SPORANOX®

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