

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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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 to treat and stop you from getting infections caused by fungi including yeasts.

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 certain fungal infections if you have a poor immune system due to a major blood disorder or bone marrow transplantation.

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

Do not use SPORANOX oral solution:

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

Tell your doctor if you are taking any medicines, before you use SPORANOX oral solution.

- **Do not use SPORANOX oral solution if** you are taking certain medicines, or within 2 weeks of stopping SPORANOX oral solution. The following list contains examples of medicines you must not take with SPORANOX oral solution, or within 2 weeks of stopping SPORANOX oral solution:

Medicines to treat problems with the heart, blood or circulation

- aliskiren, eplerenone, lercanidipine or nisoldipine (for high blood pressure)
- bepridil, ivabradine or ranolazine – (for angina)
- dabigatran or ticagrelor (for blood clots)
- disopyramide, dofetilide, dronedarone or quinidine (for irregular heart beat rhythms)

- finerenone (for kidney problems in patients with type 2 diabetes)
- lomitapide, lovastatin or simvastatin (to lower cholesterol)
- sildenafil (for pulmonary arterial hypertension)

Medicines to treat stomach problems or constipation

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

Medicines to treat headaches, sleep or mental health problems

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

Medicines to treat urinary problems

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

Medicines to treat allergies

- astemizole, mizolastine or terfenadine (for allergies)

Medicines to treat 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)

Remember – do not take any of the medicines above for 2 weeks after your last treatment with SPORANOX oral solution.

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

Stop taking SPORANOX and see your doctor immediately if any of the following symptoms of severe liver problems appear during your course of treatment:

- Severe lack of appetite, feeling sick, being sick, unusual tiredness, abdominal (stomach) pain, unusually dark urine or pale stools.

Tell your doctor immediately:

- If you have any unusual feelings of tingling, numbness or weakness in your hands or feet whilst taking SPORANOX.
- If you experience any hearing loss symptoms. In very rare cases patients taking SPORANOX have reported temporary or permanent hearing loss.

Tell your doctor if you have:

- had an allergic reaction to any other antifungal medicines
- a heart problem, including heart failure (also called congestive heart failure or CHF), SPORANOX could make it worse. If your doctor decides to give you SPORANOX, you should be told about the symptoms listed below 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
- a liver problem, such as jaundice (yellowing of the skin) as your dose of SPORANOX may have to be changed. Your doctor should give you instructions on symptoms to watch out for. If you have to take SPORANOX continuously for more than one month, your doctor may want to check your liver by doing blood tests. In addition, there may be specific medication you may not be able to take.
- Cystic fibrosis (a genetic disease affecting the lungs, pancreas, liver, kidneys and intestines).
- a kidney disorder as your dose of SPORANOX may have to be changed. In addition, there may be specific medication you may not be able to take.

Other medicines and SPORANOX oral solution

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. There are some medicines that **you should not take** whilst taking SPORANOX. These are listed above under the heading **“Do not use SPORANOX oral solution if you are:”**

Certain medicines are not recommended for use with SPORANOX oral solution.

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 to treat problems with the heart, blood or circulation

- apixaban, edoxaban, rivaroxaban or vorapaxar (for blood clots)
- atorvastatin (to lower cholesterol)
- felodipine (for high blood pressure)
- riociguat or tadalafil (for pulmonary hypertension)

Medicines to treat epilepsy, headaches or mental health problems

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

Medicines to treat urinary problems

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

Medicines to treat 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 (e.g., vinflunine, vinorelbine)

Medicines to treat tuberculosis

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

Medicines to treat human immunodeficiency virus (HIV) or hepatitis

- efavirenz or nevirapine (for HIV/AIDS)

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

Medicines used after organ transplant

- everolimus, rapamycin (also known as sirolimus), temsirolimus

Medicines to treat benign prostatic enlargement

- alfuzosin, silodosin

Medicines to treat lung problems or allergies

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

Medicines to treat erection and ejaculation problems

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

Other medicines containing:

- colchicine (for gout)
- fentanyl (for pain)
- lumacaftor/ivacaftor (for cystic fibrosis)

Remember - do not take any of the medicines above for 2 weeks after your last treatment with SPORANOX oral solution.

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.

Care needs to be taken when using SPORANOX oral solution with certain other medicines

You may be more likely to get side effects, or the dose of SPORANOX oral solution or the other medicine might need to be changed. Examples of these medicines are:

Medicines to treat problems with the heart, blood or circulation

- bosentan (for pulmonary hypertension)
- calcium channel blockers such as, dihydropyridines such as amlodipine, isradipine, nifedipine, nimodipine or diltiazem (for hypertension)
- 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 to treat stomach problems or diarrhoea

- aprepitant or netupitant (for nausea and vomiting during cancer treatment)
- 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 to treat 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 to treat urinary problems

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

Medicines to treat cancer

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

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 to treat human immunodeficiency virus (HIV) or hepatitis

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

Medicines used after organ transplant

- cyclosporine or tacrolimus

Medicines to treat benign prostatic enlargement

- dutasteride

Medicines to treat lung problems, allergies or inflammatory conditions

- bilastine or rupatadine (for allergy)
- methylprednisolone or dexamethasone, (medicines given by mouth or injection for asthma, allergies or inflammatory conditions)
- budesonide or fluticasone (for asthma, allergies)

Medicines to treat erection and ejaculation problems

- sildenafil (for erectile dysfunction)

Medicines to treat pain

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

Other medicines containing:

- 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)

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. You should use effective contraceptives to make sure that you do not become pregnant while you are taking your medicine. As SPORANOX remains in the body for some time after you stop taking it, you should continue to use some form of contraception until your next period after your treatment with SPORANOX has finished.

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, as 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/double vision or hearing loss. If you have these symptoms, do not drive or use machines.

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 SPORANOX oral solution one hour before any food or drink as this helps the body absorb the medicine.

You should swish the oral solution around in your mouth for approximately 20 seconds before swallowing it. Do not rinse your mouth after swallowing the oral solution.

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

A measuring cup graduated to indicate 10 mL is provided. Ensure you fill the cup to the 10 mL mark.

How to take SPORANOX oral solution

- **Treatment of yeast infections of the mouth, throat or gullet**

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

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

- **Treatment of yeast infections of the mouth, throat or gullet, that have already been treated with another antifungal but have still not cleared**

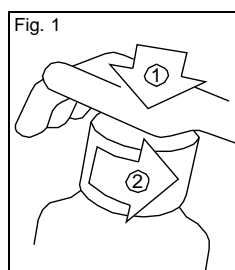
The usual dose is 1-2 measuring cups (10-20 mL) twice daily for two weeks. The treatment may be continued for an additional two weeks, if the infection does not clear in the initial two weeks of treatment. For patients on the higher dose of 400 mg (4 measuring cups) daily, treatment should be limited to 14 days, if there are no signs of improvement during this time.

- **Prevention of fungal infections**

The dose is calculated according to your body weight (5 mg per kg) given in two divided doses. Your doctor will tell you exactly how much you should take.

Directions for opening the bottle

The bottle comes with a child-proof cap, and should be opened as follows: push the plastic screw cap down, while turning it counter 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 graduations (the side that holds less) is uppermost; that is the side you have to fill. When the arrow on the side points up, the correct side is uppermost.

If you take too much SPORANOX oral solution

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 oral solution

If you forget to take your medicine, take the next dose as usual and continue your medicine as directed by your doctor. 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 oral solution can cause side effects, although not everybody gets them. Medicines can cause serious allergic reactions.

Stop taking SPORANOX and contact your doctor immediately if you have:

- any sudden wheeziness, difficulty in breathing, swelling of the face, rash, itching (especially affecting the whole body) or a severe skin disorder (widespread rashes with peeling skin and blisters in the mouth, eyes and genitals, or rashes with small pustules or blisters).
- severe lack of appetite, feeling sick, being sick, unusual tiredness, abdominal (stomach) pain, unusually dark urine, or pale stools. These may be symptoms of severe liver problems.

You should also let your doctor know immediately if you have any of the side effects below:

- Symptoms that resemble heart failure such as shortness of breath, unexpected weight gain, swelling of the legs, unusual fatigue (tiredness), repeated waking at night.
- A tingling sensation, sensitivity to light, numbness or weakness in the limbs.
- Blurred vision/double vision, ringing in your ears, lose the ability to control your urine or increased need to urinate (pass water).
- If you experience any hearing loss symptoms
- severe upper stomach pain, often with nausea and vomiting due to inflammation of the pancreas (pancreatitis).

Other side effects include:

Common side effects (occur in less than 1 in 10 patients) are:

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

Uncommon side effects (occur in less than 1 in 100 patients) are:

- certain blood disorders which may increase the risk of bleeding or bruising (possible symptoms of low levels of platelets), or infections (possible symptom of low levels of white blood cells)
- constipation
- itching, hives
- general swelling
- muscle cramps or irregular heart beat (possible symptoms of low blood levels of potassium)
- 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 with unknown frequency:

- excess of triglycerides (fats) in the blood

- hair loss
- increase in blood creatine 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

The following side effects have been reported in patients taking other formulations of SPORANOX:

- infection of the upper respiratory tract
- inflammation of the nose
- inflammation of the sinuses
- certain blood disorder which may increase the risk of infections (possible symptom of low levels of granulocytes)
- high blood sugar levels
- muscle cramps or irregular heart beat (possible symptoms of low blood levels of magnesium)
- muscle cramps or irregular heart beat (possible symptoms of high blood levels of potassium)
- confusion
- sleepiness
- tremors
- increase in heart rate
- high blood pressure
- low blood pressure
- fluid in the lungs
- difficulty speaking
- excess gas in the intestinal tract
- increases in specific liver function tests (hepatic enzyme increased)
- inflammation of the liver (hepatitis)
- yellowing of the skin (jaundice)
- excess sweating
- kidney problems
- excessive urine production
- erectile dysfunction
- general swelling
- facial swelling
- chest pain
- pain
- chills
- fatigue
- increase in blood urea levels
- abnormal urine findings

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:

HPRA Pharmacovigilance

Website: www.hpra.ie

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 SPORANOX oral solution above 25 °C.

Do not use the SPORANOX 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:

Austria: SPORANOX®
Belgium: SPORANOX®
Finland: SPORANOX®
Germany: SEMPERA®
Ireland: SPORANOX®
Italy: SPORANOX®
Luxembourg: SPORANOX®
Netherlands: TRISPORAL®
Portugal: SPORANOX®
Sweden: SPORANOX®
United Kingdom (Northern Ireland): SPORANOX®

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This leaflet was last revised in.