

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr**SPORANOX**[®] itraconazole oral solution

Read this carefully before you start taking **SPORANOX** oral solution and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **SPORANOX** oral solution.

Serious Warnings and Precautions

- **Heart Problems:** SPORANOX oral solution should not be given to patients that have or have had heart problems like congestive heart failure. Signs or symptoms of congestive heart failure may be seen with use of SPORANOX oral solution. Use of SPORANOX oral solution should be stopped if signs or symptoms of congestive heart failure are experienced (see **Serious side effects and what to do about them** table)
- **Drug Interactions:** Some medicines should NOT be taken during treatment with SPORANOX oral solution (see **Serious Drug Interactions box and the following may interact with SPORANOX oral solution** sections)
- **Liver Problems:** SPORANOX oral solution in rare cases may cause liver toxicity, liver failure and death. If liver problems are experienced, treatment with SPORANOX oral solution should be stopped (see **Serious side effects and what to do about them** table).

What is SPORANOX oral solution used for?

SPORANOX is a prescription medicine used to treat fungal infections of the mouth and throat in:

- adult HIV-positive patients
- patients with a weakened immune system.

How does SPORANOX oral solution work?

SPORANOX goes into your bloodstream and travels to the area of the infection.

What are the ingredients in SPORANOX oral solution?

Medicinal ingredients: itraconazole.

Non-medicinal ingredients: caramel flavour, cherry flavour 1 and 2, hydrochloric acid, hydroxypropyl- β -cyclodextrin, propylene glycol, purified water, sodium hydroxide, sodium saccharin, and sorbitol.

SPORANOX oral solution comes in the following dosage forms:

- Oral Solution 10 mg/mL
- You will receive the SPORANOX in a glass bottle. This bottle will contain 150 mL of solution (10 mg itraconazole per millilitre solution), along with a measuring cup.
- One full measuring cup contains 10 mL of solution, equal to 100 mg of itraconazole.

Do not use SPORANOX oral solution if:

- you have congestive heart failure, SPORANOX could make it worse.
 - If your healthcare professional decides that you need SPORANOX, be sure to get immediate medical help if you experience signs of heart failure (see **What are possible side effects from using SPORANOX oral solution?**)
- you are taking certain medicines (see **The following may interact with SPORANOX oral solution** section).
- you have had an allergic reaction to itraconazole, any of the other ingredients in SPORANOX oral solution or the container it is provided in (see **What are the ingredients in SPORANOX oral solution?**).

SPORANOX is not for everyone. Your healthcare professional will decide if SPORANOX is the right medicine for you. Some patients should not take SPORANOX because they may have certain health problems or may be taking certain medicines that could lead to serious or life-threatening health problems.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take SPORANOX oral solution. Talk about any health conditions or problems you may have, including if you:

- have high or abnormal liver enzymes, liver disease or have experienced liver toxicity with other drugs.
 - If you have liver problems, your dose of SPORANOX oral solution may have to be adjusted.
- have or have had heart disease, including congestive heart failure.
- have a kidney problem.
 - If you have a kidney disorder, your dose of SPORANOX oral solution may have to be adjusted.
- have a lung problem, including cystic fibrosis.

Other warnings you should know about:**Driving and Using Machines:**

SPORANOX oral solution can sometimes cause dizziness, blurred/double vision, or hearing loss. If you have these symptoms, do not drive, or use machines.

Children and Adolescents (under 18 years of age):

SPORANOX is not recommended for use in children as scientific information on the use of SPORANOX oral solution in children is limited.

Pregnancy

Do not take SPORANOX oral solution if you are pregnant or are planning to become pregnant. If you are taking SPORANOX oral solution, do not plan to become pregnant within 2 months of finishing your treatment.

If you are pregnant and your healthcare professional decides you need urgent treatment with SPORANOX oral solution, they will discuss with you, the possible risks of taking this medicine during pregnancy.

Serious birth defects have been seen in animals and women treated with itraconazole during pregnancy. It is not known whether itraconazole caused these defects. A reliable form of barrier contraception must always be used even if you or your partner are using other methods of contraception such as the pill or other hormonal therapy (e.g., implants, injections). SPORANOX may remain in your blood for a time after therapy is stopped. Therefore, you should continue use of a reliable form of contraception for 2 months after stopping treatment with SPORANOX.

Breast-feeding

Do not take SPORANOX oral solution if you are breast-feeding or stop breast-feeding if you are taking SPORANOX.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements, or alternative medicines.

Serious Drug Interactions

The following list of medicines must NOT be taken during your SPORANOX oral solution treatment:

DO NOT take SPORANOX oral solution if you are taking any of the following medicines:

- boosted asunaprevir to treat Hepatitis C Virus
- eplerenone, felodipine, ivabradine, ranolazine used to treat angina (crushing chest pain) or high blood pressure
- ticagrelor used to slow down blood clotting
- eletriptan used to treat migraine headaches
- lomitapide, lovastatin, simvastatin which lower cholesterol
- triazolam, sleeping pills
- disopyramide, dronedarone, quinidine, used to treat irregular heartbeat rhythms
- lurasidone, pimozide used for psychotic disorders
- methadone for severe pain or to manage addiction
- irinotecan, an anti-cancer drug
- dihydroergotamine or ergotamine (called ergot alkaloids) used in the treatment of migraine headaches
- ergometrine (ergonovine) (called ergot alkaloids) used to control bleeding and maintain uterine contraction after childbirth
- domperidone used to treat nausea and vomiting
- isavuconazole; to treat fungal infections
- naloxegol; to treat constipation caused by taking opioid painkillers
- eliglustat to treat Gaucher disease type 1 (GD1)

If you have kidney or liver problems, DO NOT take SPORANOX oral solution while taking any of the following medicines:

- colchicine, used to treat gout
- fesoterodine or solifenacin when used to control irritated urinary bladder

Medicines that must NEVER be taken while you are on SPORANOX oral solution, if you have chronic lymphocytic leukemia/small lymphocytic lymphoma and you want to newly start this medicine or are making dose adjustments:

- venetoclax

Wait at least 2 weeks after stopping SPORANOX oral solution before taking any of these medicines.

Some medicines must not be taken at the same time, and if certain medicines are taken at the same time, changes need to be made (to the dose, for example).

The following may interact with SPORANOX oral solution:

Medicines that can decrease the action of SPORANOX oral solution and are NOT recommended unless your healthcare professional feels it is necessary:

- carbamazepine, phenobarbital, phenytoin used to treat epilepsy
- isoniazid, rifabutin, rifampicin used to treat tuberculosis
- efavirenz, nevirapine used to treat HIV/AIDS

Always tell your healthcare professional if you are using any of these medicines so that the appropriate precautions can be taken.

Wait at least 2 weeks after stopping these medicines before taking SPORANOX oral solution.

Medicines NOT recommended unless your healthcare professional feels it is necessary:

- axitinib, bosutinib, cabazitaxel, cabozantinib, ceritinib, cobimetinib, crizotinib, dabrafenib, dasatinib, docetaxel, glasdegib, ibrutinib, lapatinib, nilotinib, olaparib, pazopanib, regorafenib, sunitinib, talazoparib, trabectedin, trastuzumab emtansine, vinca alkaloids used in the treatment of cancer
- riociguat, sildenafil, tadalafil, when used to treat pulmonary hypertension (increased blood pressure in the blood vessels in the lungs)
- everolimus, rapamycin (also known as sirolimus), usually given after an organ transplant
- conivaptan, tolvaptan, to treat low blood sodium
- apixaban, edoxaban, rivaroxaban to slow down blood clotting
- alfuzosin, silodosin to treat Benign Prostatic enlargement
- aliskiren to treat hypertension
- carbamazepine to treat epilepsy
- colchicine to treat gout
- darifenacin to treat urinary incontinence
- fentanyl a strong medication to treat pain
- vorapaxar used to treat heart attacks or strokes
- salmeterol to improve breathing
- tamsulosin to treat male urinary incontinence
- vardenafil to treat erectile dysfunction
- *Saccharomyces boulardii* to treat diarrhea
- lumacaftor/ ivacaftor to treat Cystic Fibrosis.

Wait at least 2 weeks after stopping these medicines before taking SPORANOX oral solution.

Medicines NOT recommended while you are on SPORANOX oral solution, when you are on a stable dose of this medicine:

- venetoclax

Wait at least 2 weeks after stopping SPORANOX oral solution before starting this medicine unless your healthcare professional feels it is necessary.

Medicines that may require a dose change (for either SPORANOX oral solution or the other medicine):

- ciprofloxacin, clarithromycin, erythromycin, antibiotics
- bosentan, digoxin, nadolol and certain calcium-channel blockers including verapamil; that act on the heart or blood vessels
- guanfacine to treat Attention Deficit Hyperactivity Disorder
- diltiazem to treat hypertension
- cilostazol, coumarins (e.g., warfarin), dabigatran; that slow down blood clotting
- budesonide, ciclesonide, dexamethasone, fluticasone, methylprednisolone (medications given by mouth, injection or inhalation for conditions such as inflammations, asthma, and allergies)
- cyclosporine, tacrolimus, temsirolimus, which are usually given after an organ transplant
- cobicistat, boosted elvitegravir, tenofovir disoproxil fumarate (TDF), maraviroc, and protease inhibitors: indinavir, ritonavir, boosted darunavir, ritonavir-boosted fosamprenavir, saquinavir; used in the treatment of HIV/AIDS
- dienogest, ulipristal used as contraceptives
- daclatasvir, telaprevir, glecaprevir/pibrentasvir; elbasvir/grazoprevir used in the treatment of Hepatitis C Virus
- bortezomib, brentuximab vedotin, busulfan, erlotinib, gefitinib, idelalisib, imatinib, ixabepilone, nintedanib, ponatinib, ruxolitinib, sonidegib, tretinoin (oral), vandetanib; used in the treatment of cancer
- alprazolam, brotizolam, buspirone, midazolam IV, perospirone, ramelteon for anxiety or to help you sleep (tranquillizer)
- alfentanil, buprenorphine, oxycodone, sufentanil; strong medications to treat pain
- repaglinide, saxagliptin to treat diabetes
- aripiprazole, haloperidol, quetiapine, risperidone to treat psychosis
- zopiclone to treat insomnia
- aprepitant, netupitant; to treat nausea and vomiting during cancer treatment
- loperamide to treat diarrhea
- fesoterodine, imidafenacin, oxybutynin, solifenacin, tolterodine; to control irritated urinary bladder
- dutasteride to treat Benign Prostatic enlargement
- sildenafil, tadalafil to treat erectile dysfunction
- praziquantel; to treat fluke and tapeworms
- bilastine, ebastine, rupatadine; for allergy
- reboxetine, venlafaxine; to treat depression and anxiety
- quinine to treat malaria
- atorvastatin to lower cholesterol

- meloxicam to treat joint inflammation and pain
- cinacalcet; to treat an over active parathyroid
- mozavaptan to treat low blood sodium
- alitretinoin (oral formulation), to treat eczema
- cabergoline to treat Parkinsons Disease
- cannabinoids; to treat nausea and vomiting, weight loss for patients with immune system problems and muscle spasms in patients with Multiple Sclerosis
- ivacaftor to treat Cystic Fibrosis
- galantamine; to treat Alzheimer's disease.

How to take SPORANOX oral solution:

You should always take SPORANOX oral solution on an empty stomach. Do NOT eat or drink for one hour after taking SPORANOX oral solution.

Do not use SPORANOX oral solution for a condition for which it was not prescribed. Do not give SPORANOX oral solution to other people, even if they have the same symptoms you have. It may harm them.

Do NOT switch to SPORANOX capsules without talking to your healthcare professional

Usual dose:

Your healthcare professional will decide the right dose for you.

Depending on your infection, you will take SPORANOX oral solution once or twice a day for as long as instructed by your healthcare professional

Use the dosing cup provided to measure the amount of solution needed.

- SPORANOX oral solution should be poured into the end of the cup containing markings which indicate dosing amounts (2.5 mL, 5 mL, and 10 mL).
- There are arrows on the sides of the dosing cup showing you which end to pour the solution into.
- You should swish the solution around in your mouth for about 20 seconds before swallowing it and avoid rinsing your mouth after taking it.

Overdose:

If you think you, or a person you are caring for, have taken too much SPORANOX, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed dose:

If you miss a dose of SPORANOX oral solution, ask your healthcare professional what you should do. Do not take a double dose to make up for a missed dose.

What are possible side effects from using SPORANOX oral solution?

These are not all the possible side effects you may have when taking SPORANOX oral solution. If you experience any side effects not listed here, tell your healthcare professional

- high triglyceride test results (fats in your blood)
- high liver test results
- nausea
- upset stomach
- vomiting
- abdominal pain
- constipation
- excess gas in the stomach
- diarrhea
- cough
- fluid in the lungs
- altered voice
- inflammation of the sinuses
- inflammation of the nose
- upper respiratory tract infection
- headache
- dizziness
- menstrual disorders
- erectile dysfunction
- confusion
- tremor
- sleepiness
- fatigue
- chills
- muscle weakness or pain
- painful joints
- chest pain
- generalized swelling
- unpleasant taste
- hair loss
- inflammation of the pancreas
- fever
- excessive sweating

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
Heart Problems: Develop shortness of breath, unusual swelling of feet, ankles or legs, sudden weight gain, unusually		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
tired, cough up white or pink phlegm, unusual fast heartbeats, begin to wake up at night.			
Liver Problems: Unusually tired, loss of appetite, yellow colour to skin or eyes, dark-coloured urine, pale stools			✓
Nerve Problems: Tingling, numbness, reduced sense of touch, weakness in the limbs, pain, pins, and needles, prickling or burning.			✓
Hypersensitivity: Skin rash, itching, hives, difficulty breathing or shortness of breath and/or, swelling of the face			✓
Severe Skin Disorder: Widespread rash with peeling skin and blisters in the mouth, eyes and genitals or rash with small pustules or blisters			✓
Blurry or double vision		✓	
Tinnitus (Ringing in ears)		✓	
Photosensitivity (oversensitivity to sunlight)			✓
Urinary Incontinence (loss of ability to control urine or urinate much more than usual)		✓	
Hearing loss symptoms^a			✓

^a Cases of temporary or permanent hearing loss have been reported in patients taking SPORANOX.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store SPORANOX oral solution at room temperature (15°C to 25°C). This medicine can be kept for only a limited time. Discard any remaining unused SPORANOX oral solution three months after opening the bottle.

Keep out of the reach and sight of children.

If you want more information about SPORANOX oral solution:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website www.janssen.com/canada, or by contacting the manufacturer at: 1-800-567-3331 or 1-800-387-8781

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