

**PART III: CONSUMER INFORMATION****PrSPORANOX®  
itraconazole oral solution**

This leaflet is Part III of a three-part "Product Monograph" published when SPORANOX® oral solution was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about SPORANOX® oral solution. Contact your doctor or pharmacist if you have any questions about the drug.

This information is for patients who have been prescribed SPORANOX® oral solution for treatment of fungal infections of the mouth and throat. This information does not take the place of discussion between you and your doctor. Only your doctor can decide if SPORANOX® treatment is right for you.

**ABOUT THIS MEDICATION****What the medication is used for:**

SPORANOX® is a prescription medication used to treat fungal infections of the mouth and throat in adult HIV-positive patients or other patients with a lowered immune system.

This Consumer Information discusses only the oral solution form of SPORANOX®. You will receive the oral solution in a glass bottle, containing 150 mL of solution (10 mg itraconazole per millilitre solution), along with a measuring cup.

**What it does:**

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

**When it should not be used:**

- if you have congestive heart failure, SPORANOX® could make it worse. If your doctor decides that you need SPORANOX®, be sure to get immediate medical help if you experience signs of heart failure (see **SIDE EFFECTS AND WHAT TO DO ABOUT THEM**)
- if you are taking certain medications (see **INTERACTIONS WITH THIS MEDICATION**)
- if you have had an allergic reaction to itraconazole or any of the other ingredients in SPORANOX® oral solution (see **What the nonmedicinal ingredients are**)

**What the medicinal ingredient is:**

The medicinal ingredient in SPORANOX® oral solution is itraconazole. One full measuring cup contains 10 millilitres of solution, corresponding to 100 milligrams of itraconazole.

**What the nonmedicinal ingredients are:**

SPORANOX® oral solution contains: hydroxypropyl- $\beta$ -cyclodextrin, sorbitol, propylene glycol, hydrochloric acid, cherry flavour 1 and 2, caramel flavour, sodium saccharin, sodium hydroxide and purified water.

**What dosage forms it comes in:**

Oral Solution 10 mg/mL

**Serious Warnings and Precautions**

- Liver toxicity (see **SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**)
- Heart problems (see **SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**)
- Drug interactions (see **INTERACTIONS WITH THIS MEDICATION**)

SPORANOX® treatment is not for everyone. Your doctor will decide if SPORANOX® is the right treatment for you. Some patients should not take SPORANOX® oral solution because they may have certain health problems or may be taking certain medications that could lead to serious or life-threatening medical problems.

Tell your doctor about any other medical conditions you have had, especially heart, lung, liver or kidney conditions.

- If you have a liver problem, your dose of SPORANOX® oral solution may have to be adjusted;
- If you have a kidney disorder, your dose of SPORANOX® oral solution may have to be adjusted.

Also tell your doctor and pharmacist the name of all the prescription and non-prescription medications you are taking, including dietary supplements and herbal remedies.

BEFORE you use SPORANOX® oral solution, let your doctor or pharmacist know if:

- you have elevated or abnormal liver enzymes or active liver disease, or have experienced liver toxicity with other drugs;
- you have or have had heart disease, including congestive heart failure;
- you have cystic fibrosis;
- you have ever had an allergic reaction to itraconazole or any of the other ingredients in SPORANOX® oral solution.

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

Since scientific information on the use of SPORANOX® oral solution in children is limited, it is not recommended for use in children.

**Pregnancy**

Do not take SPORANOX® oral solution if you are pregnant (unless your doctor knows you are pregnant and decides you need SPORANOX®) or planning to become pregnant within 2 months after you have finished your treatment.

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<sup>®</sup>.

### **Breast-feeding**

Do not take SPORANOX<sup>®</sup> oral solution if you are breast-feeding or discontinue nursing if you are taking SPORANOX<sup>®</sup>. SPORANOX<sup>®</sup> is found in human breast milk.

## **INTERACTIONS WITH THIS MEDICATION**

Tell your doctor or pharmacist what medications you are currently taking. In particular, some medications must not be taken at the same time, and if certain medications are taken at the same time, changes need to be made (to the dose, for example). A wide variety of drugs may interact with SPORANOX<sup>®</sup> oral solution.

*Never take SPORANOX<sup>®</sup> oral solution if you are taking any of the following medications:*

- 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 heart beat 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 child birth
- domperidone used to treat nausea and vomiting
- naloxegol; to treat constipation caused by taking opioid painkillers
- eliglustat to treat Gaucher disease type 1 (GD1)

*If you have kidney or liver impairment, never take SPORANOX<sup>®</sup> oral solution while taking any of the following medications:*

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

Wait at least 2 weeks after stopping SPORANOX<sup>®</sup> oral solution before taking any of these medications.

*Medications that can decrease the action of SPORANOX<sup>®</sup> oral solution and are not recommended unless your doctor 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.

You should therefore always tell your doctor if you are using any of these products so that the appropriate measures can be taken.

Wait at least 2 weeks after stopping these medications before taking SPORANOX<sup>®</sup> oral solution.

*Medications not recommended unless your doctor feels it is necessary:*

- axitinib, bosutinib, cabazitaxel, ceritinib, cobimetinib, crizotinib, dabrafenib, dasatinib, docetaxel, ibritinib, lapatinib, nilotinib, olaparib, pazopanib, regorafenib, sunitinib, 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, 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
- simeprevir to treat Hepatitis C Virus
- 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 medications before taking SPORANOX<sup>®</sup> oral solution.

*Medications that may require a dose change (for either SPORANOX<sup>®</sup> oral solution or the other medication):*

- 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, 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 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.

Always tell your doctor, nurse or pharmacist if you are taking any other medications, either prescription or over-the-counter, herbal medications or natural health products.

### PROPER USE OF THIS MEDICATION

You should always take SPORANOX® oral solution without food. You should 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 doctor.

#### Usual dose:

Your doctor 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 prescribed by your doctor.

Use the dosing cup provided in your SPORANOX® package to accurately 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 approximately 20 seconds before swallowing it, and avoid rinsing your mouth after taking it.

#### Overdose:

In case of drug overdose, contact a healthcare practitioner (e.g., doctor), hospital emergency department, or regional poison control centre, even if there are no symptoms.

#### Missed dose:

If you forget to take, or miss doses of SPORANOX® oral solution, ask your doctor what you should do with the missed doses. Do not double dose.

### SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The most common side effects that cause people to stop treatment either for a short time or completely include: skin rash, high triglyceride test results (fats in your blood), high liver test results, and digestive system problems (such as nausea, bloating, and diarrhea).

Other side effects that may occur with SPORANOX® treatment include upset stomach, vomiting, abdominal pain, constipation or excess gas in stomach, 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, pain, chest pain, swelling, generalized swelling, unpleasant taste, hair loss, inflammation of the pancreas, fever, excessive sweating may also occur.

Report any side effects to your doctor or pharmacist.

### SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist immediately		Stop taking drug and call your doctor or pharmacist immediately
	Only if severe	In all cases	
<p><i>The following side effects are all uncommon:</i></p> <p><b>Heart Problems</b></p> <ul style="list-style-type: none"> <li>• Develop shortness of breath</li> <li>• Unusual swelling of feet, ankles or legs</li> <li>• Sudden weight gain</li> <li>• Unusually tired</li> <li>• Cough up white or pink phlegm</li> <li>• Unusual fast heartbeats</li> <li>• Begin to wake up at night</li> </ul>		<ul style="list-style-type: none"> <li>✓</li> <li>✓</li> <li>✓</li> <li>✓</li> <li>✓</li> <li>✓</li> <li>✓</li> </ul>	

## SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

<b>Liver Problems</b> <ul style="list-style-type: none"> <li>Unusually tired</li> <li>Loss of appetite</li> <li>Nausea</li> <li>Abdominal pain</li> <li>Vomiting</li> <li>Yellow colour to skin or eyes</li> <li>Dark-coloured urine</li> <li>Pale stools</li> </ul>			<ul style="list-style-type: none"> <li>✓</li> <li>✓</li> <li>✓</li> <li>✓</li> <li>✓</li> <li>✓</li> <li>✓</li> <li>✓</li> </ul>
<b>Nerve Problems</b> <ul style="list-style-type: none"> <li>Tingling</li> <li>Numbness</li> <li>Reduced sense of touch</li> <li>Weakness in the limbs</li> <li>Pain</li> <li>Pins and needles</li> <li>Prickling or burning</li> </ul>			<ul style="list-style-type: none"> <li>✓</li> <li>✓</li> <li>✓</li> <li>✓</li> <li>✓</li> <li>✓</li> <li>✓</li> </ul>
<b>Hypersensitivity</b> <ul style="list-style-type: none"> <li>Skin rash</li> <li>Itching</li> <li>Hives</li> <li>Difficulty breathing or shortness of breath and/or</li> <li>Swelling of the face</li> </ul>			<ul style="list-style-type: none"> <li>✓</li> <li>✓</li> <li>✓</li> <li>✓</li> <li>✓</li> </ul>
<b>Severe Skin Disorder</b> <ul style="list-style-type: none"> <li>Widespread rash with peeling skin and blisters in the mouth, eyes and genitals or</li> <li>Rash with small pustules or blisters</li> </ul>			<ul style="list-style-type: none"> <li>✓</li> <li>✓</li> </ul>
<b>Other</b> <ul style="list-style-type: none"> <li>Blurry or double vision</li> <li>Ringing in ears</li> <li>Oversensitivity to sunlight</li> <li>Loss of ability to control urine or urinate much more than usual</li> <li>Hearing loss symptoms<sup>a</sup></li> </ul>		<ul style="list-style-type: none"> <li>✓</li> <li>✓</li> <li>✓</li> <li>✓</li> </ul>	<ul style="list-style-type: none"> <li>✓</li> <li>✓</li> <li>✓</li> <li>✓</li> </ul>

<sup>a</sup> Cases of temporary or permanent hearing loss have been reported in patients taking SPORANOX<sup>®</sup>.

*This is not a complete list of side effects. For any unexpected effects while taking SPORANOX<sup>®</sup> oral solution, contact your doctor or pharmacist.*

## HOW TO STORE IT

Keep all medications, including SPORANOX<sup>®</sup> oral solution, out of the reach and sight of children.

Store SPORANOX<sup>®</sup> oral solution at room temperature (15°C - 25°C). This medication can be kept for only a limited time. Discard any remaining unused SPORANOX<sup>®</sup> oral solution three months after opening the bottle.

## 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 ([www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting](http://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting)) for more information on how to report online, by mail or by fax
- Call 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.

## MORE INFORMATION

For questions, concerns or the full Product Monograph, go to: [www.janssen.com/canada](http://www.janssen.com/canada)

or contact the manufacturer, Janssen Inc., at: 1-800-567-3331 or 1-800-387-8781.

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