

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **SPORANOX®**

Itraconazole capsules

This patient medication information is written for the person who will be taking **SPORANOX**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This patient medication information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **SPORANOX**, talk to a healthcare professional.

Serious warnings and precautions box

- **Heart Problems:** You should not take SPORANOX if you have or have had heart problems like congestive heart failure. Signs or symptoms of congestive heart failure may be seen with use of SPORANOX. Stop taking SPORANOX and contact your healthcare professional right away if you have signs or symptoms of congestive heart failure (see **Serious side effects and what to do about them** table).
- **Drug Interactions:** Some medicines should NOT be taken during treatment with SPORANOX (see **Serious Drug Interactions** box and **The following may also interact with SPORANOX** sections).
- **Liver Problems:** SPORANOX in rare cases may cause liver toxicity, liver failure and death. Stop taking SPORANOX and contact your healthcare professional right away if you have signs or symptoms of liver problems (see **Serious side effects and what to do about them** table).

What SPORANOX is used for:

- SPORANOX is a medicine used to treat fungal infections of the skin, mouth, eyes, nails or internal organs.

How SPORANOX works:

SPORANOX goes into your bloodstream and travels to the site of the infection and kills the fungus causing your disease.

Recovery time depends on disease type and severity. For fungal nail infections, improvements may not be seen until several months after the treatment period has finished.

The ingredients in SPORANOX are:

Medicinal ingredients: itraconazole

Non-medicinal ingredients: D&C Red No.22 (eosine), D&C Red No.28 (phloxine B), FD&C Blue No.1 (brilliant blue), FD&C Blue No.2 (indigotin), gelatin, hypromellose, macrogol and sugar spheres (composed of maize starch, purified water and sucrose), and titanium dioxide.

SPORANOX comes in the following dosage forms:

- Capsule (pink and blue), with each capsule containing 100 mg of itraconazole

Do not use SPORANOX if:

- you have or have had congestive heart failure. SPORANOX could make it worse.
 - If you have congestive heart failure and you are being treated for a fungal infection of the skin or nails, you should not take SPORANOX.
 - If you are being treated for another kind of fungal infection and your healthcare professional decides that you need SPORANOX, be sure to get immediate medical help if you experience signs of heart failure (see **Possible side effects from using SPORANOX?**).
- you are taking certain medicines that must not be taken with SPORANOX (see **The following may interact with SPORANOX** section).
- you have ever had an allergic reaction to itraconazole or any of the other ingredients in SPORANOX (see **The ingredients in SPORANOX are?**).
- you have ever had an allergic reaction to other medicines you have taken to treat a fungal infection.
- you have a fungal infection of the skin or nails and are pregnant or planning to become pregnant.

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

- have kidney problems.
- have low white blood cell count, AIDS, or are an organ transplant patient.
- have a lung problem, including cystic fibrosis.
- have reduced stomach acidity. This may be due to a condition that affects your ability to produce stomach acids (such as achlorhydria) or if you are taking other medications that lowers stomach acidity.

Other warnings you should know about:

- **Driving and Using Machines:**
SPORANOX can cause dizziness, blurred or 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. There is limited information on the use of SPORANOX in children.
- **Pregnancy**
 - Do not take SPORANOX if you are pregnant or are planning to become pregnant. It may harm your unborn baby.

- If you are pregnant and your healthcare professional decides you need urgent treatment with SPORANOX, 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 SPORANOX during pregnancy. It is not known whether SPORANOX caused these defects.
- If you are taking SPORANOX, do not plan to become pregnant within 2 months of finishing your treatment.
- If you are able to become pregnant and are taking SPORANOX for the treatment of fungal skin or nail infections:
 - o You must always use a reliable form of barrier birth control along with other methods of birth control (such as oral birth control pills or other hormonal methods like implants, injections).
 - o You should also continue using a reliable form of birth control for 2 months after stopping treatment with SPORANOX. SPORANOX may remain in your blood for a time after therapy is stopped.
- **Breastfeeding**
 - Do not take SPORANOX if you are breast-feeding. SPORANOX passes into your breastmilk and may harm your baby.
 - Talk to your healthcare professional about the best way to feed your baby during treatment with 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 treatment:

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

- boosted asunaprevir, used in the treatment of Hepatitis C Virus
- eplerenone, felodipine, ivabradine, ranolazine, used to treat angina (crushing chest pain) or high blood pressure
- ticagrelor, apixaban, rivaroxaban, used to slow down blood clotting
- lomitapide, lovastatin, simvastatin, used to lower cholesterol
- triazolam, used to treat insomnia
- lurasidone, pimozide, used for psychotic disorders
- methadone, used for severe pain or to manage addiction
- 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
- eletriptan, used to treat migraine headaches
- irinotecan, used to treat cancer
- disopyramide, dronedarone, quinidine, used to treat irregular heart beat rhythms
- domperidone, used to treat nausea and vomiting
- isavuconazole, used to treat fungal infections
- naloxegol, used to treat constipation caused by taking opioid painkillers
- eliglustat, used to treat Gaucher disease type 1 (GD1)

If you have kidney or liver problems, DO NOT take SPORANOX 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, 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 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 also interact with SPORANOX:

Medicines that can decrease the action of SPORANOX 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.

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

- axitinib, bosutinib, cabazitaxel, cabozantinib, ceritinib, cobimetinib, crizotinib, dabrafenib, dasatinib, docetaxel, entrectinib, glasdegib, ibrutinib, lapatinib, nilotinib, olaparib, pazopanib, regorafenib, sunitinib, talazoparib, trabectedin, trastuzumab emtansine, vinca alkaloids, used to treat cancer
- riociguat, sildenafil, tadalafil, when used to treat pulmonary hypertension (increased blood pressure in the blood vessels in the lungs)
- everolimus, sirolimus, used to prevent rejection of a transplant
- conivaptan, tolvaptan, used to treat low blood sodium
- edoxaban, used to slow down blood clotting
- alfuzosin, silodosin, used to treat benign prostatic enlargement
- aliskiren, used to treat high blood pressure
- carbamazepine, used to treat epilepsy
- colchicine, used to treat gout
- darifenacin, used to treat urinary incontinence
- fentanyl, a strong medication used to treat pain
- vorapaxar, used to treat heart attacks or strokes
- salmeterol, used to improve breathing
- tamsulosin, used to treat male urinary incontinence

- vardenafil, used to treat erectile dysfunction
- *Saccharomyces boulardii*, used to treat diarrhea
- lumacaftor/ ivacaftor, used to treat Cystic Fibrosis.

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

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

- venetoclax

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

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

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

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

How to take SPORANOX:

- Take SPORANOX exactly as your healthcare professional tells you. Always take SPORANOX right after a full meal because it is better taken up by the body this way. Swallow the capsules whole with some water.
- If you are taking acid-neutralizing medicines (i.e., antacids), you should take these at least 1 hour before, or 2 hours after your SPORANOX. For the same reason, if you take medicines that stop the production of stomach acid, you should take your SPORANOX with a non-diet cola beverage.
- Do NOT switch to itraconazole oral solution without talking to your healthcare professional.

Usual dose:

- Your healthcare professional will decide the right SPORANOX dose for you, and the length of SPORANOX treatment. This may depend on the type of fungus and the place of your infection.
- Do not skip any doses. Be sure to finish all your SPORANOX as instructed by your healthcare professional.

Overdose:

If you think you, or a person you are caring for, have taken too much SPORANOX, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

- If you missed a dose of SPORANOX, take it as soon as you remember. This will help to keep a constant amount of medication in your blood.
- But, if it is almost time for your next dose, skip the missed dose and continue with your next scheduled dose. Do not take two doses at the same time to make up for a forgotten dose.

Possible side effects from using SPORANOX?

These are not all the possible side effects you may have when taking SPORANOX. 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

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
Blurry or Double Vision		✓	
Temporary or permanent Hearing loss			✓
Heart Problems: Develop shortness of breath, unusual swelling of feet, ankles or legs, sudden weight gain, unusually tired, cough up white or pink phlegm, begin to wake up at night, unusually fast or slow heartbeats		✓	

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Hypersensitivity (allergic reaction): Skin rash, itching, hives, difficulty breathing or shortness of breath and/or, swelling of the face			✓
Liver Problems: Unusually tired, loss of appetite, nausea, abdominal pain, vomiting, 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.			✓
Photosensitivity (oversensitivity to sunlight)			✓
Severe Skin Disorder: Widespread rash with peeling skin and blisters in the mouth, eyes and genitals or rash with small pustules or blisters			✓
Tinnitus (Ringing in ears)		✓	
Urinary Incontinence (loss of ability to control urine or urinate much more than usual)		✓	

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 (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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

Storage:

- Store SPORANOX capsules at room temperature (15°C to 30°C) in a dry place protected from light.
- Keep out of the reach and sight of children.

If you want more information about SPORANOX:

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

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