

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr**SPORANOX**[®] Itraconazole capsules

Read this carefully before you start taking **SPORANOX** capsules 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** capsules.

Serious Warnings and Precautions

- **Heart Problems:** SPORANOX capsules 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 capsules. Use of SPORANOX capsules 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 capsules (see **Serious Drug Interactions box and the following may interact with SPORANOX capsules** sections)
- **Liver Problems:** SPORANOX capsules in rare cases may cause liver toxicity, liver failure and death. If liver problems are experienced, treatment with SPORANOX capsules should be stopped (see **Serious side effects and what to do about them** table).

What is SPORANOX capsules used for?

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

How does SPORANOX capsules work?

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.

What are the ingredients in SPORANOX capsules?

Medicinal ingredients: itraconazole

Non-medicinal ingredients: hypromellose, macrogol and sugar spheres (composed of maize starch, purified water and sucrose), 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, and titanium dioxide.

SPORANOX capsules comes in the following dosage forms:

pink and blue capsules, with each capsule containing 100 mg of itraconazole

Do not use SPORANOX capsules if:

- you have 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 **What are possible side effects from using SPORANOX capsules?**)
- you are taking certain medicines (see **The following may interact with SPORANOX capsules** section)
- you have had an allergic reaction to itraconazole, any of the other ingredients in SPORANOX capsules or the container it is provided in (see **What are the ingredients in SPORANOX capsules?**)
- you have a fungal infection of the skin or nails and are pregnant or planning to become pregnant

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 if taken together with SPORANOX.

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

- have or have had heart disease, including congestive heart failure.
- have high or abnormal liver enzymes or liver disease or have experienced liver toxicity with other drugs.
 - If you have liver problems, your dose of SPORANOX capsules may have to be adjusted
- Have a kidney problem.
 - If you have a kidney disorder, your dose of SPORANOX capsules may have to be adjusted
- are a neutropenic (low white blood cell count), AIDS, or organ transplant patient. The dose of SPORANOX capsules may have to be adjusted
- have a lung problem, including cystic fibrosis.

Other warnings you should know about:

Driving and Using Machines:

SPORANOX capsules 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 capsules in children is limited.

Pregnancy

Do not take SPORANOX if you are pregnant or are planning to become pregnant.

If you are taking SPORANOX, 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, 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. If you are able to become pregnant and are receiving SPORANOX for the treatment of fungal skin or nail infections, 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 capsules 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 capsules treatment:

DO NOT take SPORANOX capsules 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 used to slow down blood clotting
- lomitapide, lovastatin, simvastatin which lower cholesterol
- triazolam, sleeping pills
- lurasidone, pimozide used for psychotic disorders
- methadone 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, an anti-cancer drug
- disopyramide, dronedarone, quinidine, used to treat irregular heart beat rhythms
- 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 capsules 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 capsules, 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 capsules 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).

Medicines that can decrease the action of SPORANOX capsules 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 capsules.

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 capsules.

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

- venetoclax

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

Medicines that may require a dose change (for either SPORANOX capsules 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 to treat 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 overactive 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 capsules:

Always take SPORANOX capsules 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 capsules. For the same reason, if you take medicines that stop the production of stomach acid, you should take your SPORANOX capsules with a non-diet cola beverage.

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

Do NOT switch to SPORANOX 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, depending on the type of fungus and the place of your infection. Do not skip any doses. Be sure to finish all your SPORANOX capsules 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, or regional poison control centre immediately, even if there are no symptoms.

Missed dose:

If you forget to take or miss a dose of SPORANOX capsules, 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 capsules?

These are not all the possible side effects you may have when taken SPORANOX capsules. 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 tired, cough up white or pink phlegm, unusual fast heartbeats, begin to wake up at night.		✓	
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,			✓

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	
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:

Keep out of the reach and sight of children.

Store SPORANOX capsules at room temperature (15°C to 30°C) in a dry place protected from light.

If you want more information about SPORANOX capsules:

- 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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