PART III: CONSUMER INFORMATION

PrSPORANOX®
itraconazole capsules

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

This information is for patients who have been prescribed SPORANOX® capsules for treatment of fungal infections of the skin, mouth, eyes, nails or internal organs. 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 skin, mouth, eyes, nails or internal organs.

This Consumer Information discusses only the capsule form of SPORANOX®. You will get these capsules in a medicine bottle or a SPORANOX® PULSEPAK®. The PULSEPAK® contains 28 capsules for treatment of your fungal nail infection.

What it does:
SPORANOX® goes into your bloodstream and travels to the site of the infection and kills the fungus causing your disease. Recovery time depends on the disease type and severity.

For fungal nail infections, improved nails may not be obvious for several months after the treatment period is finished because it usually takes about 6 months to grow a new fingernail and 12 months to grow a new toenail. Also, SPORANOX® is present in the nail for a long period of time after treatment has stopped.

With skin infections, the lesions will completely disappear only a few weeks after the end of the treatment. This is typical of fungal patches: the drug kills the fungus itself, but the lesion disappears together with regrowth of healthy skin.

When it should not be used:
- 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 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® capsules (see **What the nonmedicinal ingredients are**)
- if you have a fungal infection of the skin or nails and are pregnant or planning to become pregnant

What the medicinal ingredient is:
itraconazole

What the nonmedicinal ingredients are:
The capsules contain sugar spheres (composed of maize starch, purified water and sucrose), hypromellose and macrogol. The capsule itself is composed of titanium dioxide, FD&C Blue No.1 (brilliant blue), FD&C Blue No.2 (indigotin), D&C Red No.22 (eosine), D&C Red No.28 (phloxine B) and gelatin.

What dosage forms it comes in:
pink and blue capsules, with each capsule containing 100 mg of itraconazole

WARNINGS AND PRECAUTIONS

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® capsules because they may have certain health problems or may be taking certain medications that could lead to serious or life-threatening medical problems if taken together with SPORANOX®.

Tell your doctor about any other medical conditions you have, or have had, especially heart, lung, liver or kidney conditions.
- If you have a liver problem, your dose of SPORANOX® capsules may have to be adjusted;
- If you have a kidney disorder, your dose of SPORANOX® capsules 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® capsules let your doctor or pharmacist know if:
- you have or have had heart disease, including congestive heart failure;
- you have elevated or abnormal liver enzymes or active liver disease, or have experienced liver toxicity with other drugs;
- you are a neutropenic (low white blood cell count), AIDS, or organ transplant patient. The dose of SPORANOX® capsules may have to be adapted;
- you have cystic fibrosis;
- you have ever had an allergic reaction to itraconazole or any of the other ingredients in SPORANOX® capsules.

SPORANOX® capsules 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® capsules in children is limited, it is not recommended for use in children under 18 years of age.

Pregnancy

Do not take SPORANOX® 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. 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 discontinue nursing if you are taking SPORANOX®.
SPORANOX® 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® capsules.

Never take SPORANOX® capsules if you are taking any of the following medications:

- 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
- 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® capsules 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® capsules before taking any of these medications.

Medications that can decrease the action of SPORANOX® capsules 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® capsules.

Medications not recommended unless your doctor feels it is necessary:

- axitinib, bosutinib, cabazitaxel, ceritinib, cobimetinib, crizotinib, dabrafenib, dasatinib, docetaxel, ibrutinib, 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® capsules.

*Medications that may require a dose change (for either SPORANOX® capsules or the other medic*ation*):*

- 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, 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

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 medications (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 medications 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 doctor.

The SPORANOX® PULSEPAK®

If you use the PULSEPAK®, you will take SPORANOX® capsules for 1 week and then take no SPORANOX® treatment for the next 3 weeks before repeating the 1-week treatment. This is called "pulse dosing." The SPORANOX® PULSEPAK® contains enough medication for one "pulse" (1 week of treatment). The SPORANOX® PULSEPAK® is used only for fungal nail infections.

The SPORANOX® PULSEPAK® comes with special instructions. It contains 7 blister cards — one for each day of treatment. Each card contains 4 capsules. Looking at the back of the card, fold it back along the dashed line and peel away the backing so that you can remove 2 capsules.

Dosing for Fungal Nail Infection:

- Take 2 capsules in the morning and 2 capsules in the evening. This means you will take 4 capsules a day for 7 days. At the end of 7 days, you will have taken all of the capsules in the PULSEPAK® box.

- After you finish the PULSEPAK®, do not take any SPORANOX® capsules for the next 3 weeks. Even though you are not taking any capsules during this time, SPORANOX® treatment keeps working inside your nails to help fight the fungal infection.

- You will need more than one "pulse" to treat your fungal nail infection. When your doctor prescribes another pulse treatment, be sure to get your refill before the end of week 4.

- Nail lesions take up to 6 to 9 months to disappear after the end of treatment. Once the drug kills the fungus, the nail still needs to grow back, and regrowth takes many months. You should therefore stop treatment as prescribed by your doctor, even though you do not see any improvement.

Usual dose:

Your doctor 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. You will receive either a bottle of capsules or a PULSEPAK®. Do not skip any doses. Be sure to finish all your SPORANOX® capsules as prescribed by your doctor.

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® capsules, 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 or 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 *The following side effects are all uncommon:*	Talk with your doctor or pharmacist immediately		Stop taking drug and call your doctor or pharmacist immediately
	Only if severe	In all cases	
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			✓
• 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			✓
Other			
• Blurry or double vision		✓	
• Ringing in ears		✓	
• Oversensitivity to sunlight			✓
• 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®

This is not a complete list of side effects. For any unexpected effects while taking SPORANOX® capsules, contact your doctor or pharmacist.

HOW TO STORE IT

Keep all medications, including SPORANOX® capsules, out of the reach and sight of children.

Store SPORANOX® capsules and the PULSEPAK® at room temperature (15°C-30°C) in a dry place protected from light.

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) for more information on how to report online, by mail or by fax: Call toll-free at 1-866-234-2345

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

This leaflet was prepared by Janssen Inc.
Toronto, Ontario M3C 1L9

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