

SPORANOX[®] ORAL SOLUTION

Itraconazole 10mg/mL

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What SPORANOX[®] is used for

SPORANOX oral solution is a medicine used:

- to treat yeast infections of the mouth, throat and foodpipe (esophagus) in people with a lowered resistance;
- to prevent certain fungal infections in people who may have a lowered resistance due to a major blood disorder or bone marrow transplantation.

Your doctor may have prescribed SPORANOX Oral Solution for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

How SPORANOX[®] works

SPORANOX works by killing or stopping the growth of the fungus that causes the infection.

Before you use SPORANOX[®]

- *When you must not use it*

Do not take SPORANOX oral solution:

- if you know you are hypersensitive (allergic) to it;
- if you are pregnant (unless your doctor knows you are pregnant and decides you need SPORANOX);
- if you are of child bearing age and could become pregnant, you should take adequate contraceptive precautions to make sure that you do not become pregnant while you are taking your medicine. As SPORANOX remains in the body

for some time after you stop taking it, you should continue to use contraception until your next period after your treatment with SPORANOX oral solution is finished.

- if you have a condition called heart failure (also called congestive heart failure or CHF), SPORANOX could make it worse. If your doctor decides that you need to take SPORANOX even if you have this condition, be sure to get immediate medical help if you have shortness of breath, unexpected weight gain, swelling of the legs, unusual fatigue, or begin to wake up at night.

Also, do not use certain medications if you are on SPORANOX oral solution. There are many medications that interact with SPORANOX oral solution. Please refer to the section "Before you start to use it", subsection "Taking other medicines".

Pregnancy and Breastfeeding

Pregnancy

Do not use SPORANOX oral solution if you are pregnant.

If you are of child bearing age and could become pregnant, you should take adequate contraceptive precautions to make sure that you do not become pregnant while you are taking your medicine. As SPORANOX remains in the body for some time after you stop taking it, you should continue to use some form of contraception until your next period after your treatment with SPORANOX oral solution is finished.

Breastfeeding

If you are breast-feeding, tell your doctor before taking SPORANOX oral solution; very small amounts of SPORANOX could be present in your milk.

- *Before you start to use it*

Always tell your doctor or pharmacist if you are taking any other medicine

because taking some medicines together can be harmful.

Tell your doctor if you know you have a liver problem. The dose of SPORANOX oral solution may need to be adjusted.

Stop taking SPORANOX and see your doctor immediately should any of the following symptoms appear during the SPORANOX treatment: lack of appetite, nausea, vomiting, tiredness, abdominal pain, yellow color to skin or eyes, pale stools (bowel movements) or very dark urine. If you have to take SPORANOX oral solution your doctor may also ask you to have your blood checked regularly. The reason for this is to rule out liver disorders in timely fashion, since such disorders can occur very rarely.

Tell your doctor if you have a heart problem. Tell your doctor immediately if you develop shortness of breath, unexpected weight gain, swelling of the legs, unusual fatigue, or begin to wake up at night as these may be symptoms of heart failure.

Tell your doctor if you have a kidney disorder. The dose of SPORANOX oral solution may need to be adjusted.

Tell your doctor or get medical assistance immediately if you have a severe allergic reaction (characterized by significant skin rash, itching, hives, difficulty breathing and/or swollen face) while taking SPORANOX oral solution.

Stop taking SPORANOX oral solution and tell your doctor immediately if you become oversensitive to sunlight.

Stop taking SPORANOX oral solution and tell your doctor immediately if you experience a severe skin disorder such as a widespread rash with peeling skin and blisters in the mouth, eyes and genitals, or a rash with small pustules or blisters.

Stop taking SPORANOX oral solution and tell your doctor immediately if you develop any feelings of tingling, diminished sensation or weakness in your limbs, or other problems with the nerves in the arms or legs.

Tell your doctor if you had experienced an allergic reaction to SPORANOX or another antifungal.

Tell your doctor if you have cystic fibrosis before using SPORANOX oral solution.

Stop taking SPORANOX oral solution and tell your doctor immediately if you experience any hearing loss symptoms. In very rare cases, patients taking SPORANOX have reported temporary or permanent hearing loss.

Tell your doctor if your vision gets blurry or you see double, if you hear a ringing in your ears, if you lose the ability to control your urine or urinate much more than usual.

- Taking other medicines

Tell your doctor or pharmacist what medicines you are currently taking. In particular, 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 must never be taken while you are on SPORANOX oral solution:

- terfenadine, astemizole, mizolastine; for allergy;
- bepridil, felodipine, nisoldipine, lercanidipine, ivabradine, ranolazine, eplerenone; to treat angina (crushing chest pain) or high blood pressure;
- cisapride, to treat certain digestive problems;
- simvastatin, lomitapide, lovastatin; which lower the cholesterol;
- midazolam (oral), triazolam; sleeping pills;
- disopyramide, dronedarone, quinidine dofetilide; to treat irregular heart beat rhythms;
- lurasidone, pimozide, sertindole; used for psychotic disorders;

- levacetylmethadol (levomethadyl), methadone; for severe pain or to manage addiction;
- halofantrine; to treat malaria;
- irinotecan, mocertinib, anti-cancer drugs;
- dihydroergotamine or ergotamine (called ergot alkaloids) used in the treatment of migraine headaches;
- ergometrine (ergonovine) or methylethergometrine (methylethergonovine) (called ergot alkaloids) used to control bleeding and maintain uterine contraction after child birth;
- domperidone; to treat nausea and vomiting;
- isavuconazole; to treat fungal infections;
- naloxegol; to treat constipation caused by taking opioid painkillers;
- avanafil; to treat erectile dysfunction;
- dapoxetine; to treat premature ejaculation.
- Finerenone; to treat kidney problems in patients with type 2 diabetes
- Voclosporin; to treat lupus-related kidney problems

Medicines that must never be taken while you are on SPORANOX oral solution, if you have kidney or liver impairment:

- colchicine; to treat gout;
- fesoteridine or solifenacin; when used to control irritated urinary bladder;
- telithromycin; an antibiotic.

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

Medicines that are not recommended, because they can decrease the action of SPORANOX oral solution:

- carbamazepine, phenytoin, phenobarbital; to treat epilepsy;
- rifampicin, rifabutin, isoniazid; to treat tuberculosis;
- efavirenz, nevirapine; 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 medicines before taking SPORANOX oral solution.

Medicines not recommended unless your doctor feels it is necessary:

- axitinib, bosutinib, carbazotaxel, cabozantinib, ceritinib, cobimetinib, crizotinib, dabrafenib, dasatinib, docetaxel, entrectinib, glasdegib, ibrutinib, lapatanib, nilotinib, olaparib, pazopanib, regorafenib, sunitinib, talazoparib, trastuzumab emtansine, vinca alkaloids, trabectedin; 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;
- bedaquiline; rifabutin; to treat tuberculosis;
- conivaptan, tolvaptan; to treat low blood sodium;
- apixaban, edoxaban, rivaroxaban; to slow down blood clotting;
- alfuzosin, sildosin; 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 medicine to treat pain;
- salmeterol; improve breathing;
- tamsulosin; to treat male urinary incontinence;
- vardenafil; to treat erectile dysfunction.

- *Saccharomyces boulardii*; used to treat diarrhea;

- lumacaftor/ ivacaftor; used to treat Cystic Fibrosis.

- Medicines to treat chronic lymphocytic leukemia/small lymphocytic lymphoma, or any time of treatment for acute myeloid leukemia such as venetoclax

Wait at least 2 weeks after stopping SPORANOX oral solution before starting these medicines unless your doctor feels it is necessary.

Medicines that may require a dose change (for either SPORANOX oral

solution or the other medicine), such as:

- ciprofloxacin, clarithromycin, erythromycin; antibiotics;
- delamanid, used to treat tuberculosis;
- trimetrexate; used to treat pneumonia in patients with immune system problems;
- bosentan, digoxin, nadolol, and certain calcium-channel blockers including verapamil; some medicines that act on the heart or blood vessels;
- guanfacine; used to treat Attention Deficit Hyperactivity Disorder;
- diltiazem; used to treat hypertension;
- coumarins (e.g. warfarin), cilostazol, dabigatran; that slow down blood clotting;
- methylprednisolone, budesonide, ciclesonide, fluticasone or dexamethasone (medicines 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 fumerate (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;
- boosted asunaprevir, boceprevir, daclatasvir, vaniprevir; used in the treatment of Hepatitis C Virus;
- bortezomib, brentuximab vedotin, busulphan, erlotinib, gefitinib, idelalisib, tretinoin (oral), imatinib, ixabepilone, nintedanib, panobinostat, pemigatinib, ponatinib, ruxolitinib, sonidegib, vandetanib; certain medicines used in the treatment of cancer;
- buspirone, perospirone, ramelteon, midazolam IV, alprazolam, brotizolam; for anxiety or to help you sleep (tranquillizer);
- alfentanil, buprenorphine, oxycodone, sufentanil; strong medicines to treat pain;
- repaglinide, saxagliptin; to treat diabetes;
- aripiprazole, cariprazine, haloperidol, quetiapine, risperidone; to treat psychosis;
- suvorexant, zopiclone; to treat insomnia;
- aprepitant, netupitan; to treat nausea and vomiting during cancer treatment;
- loperamide; to treat diarrhea;
- fesoterodine, imidafenacin, solifenacin, tolterodine; certain medicines to control irritated urinary bladder;
- dutasteride; used to treat Benign Prostatic enlargement;
- sildenafil, tadalafil, udenafil; to treat erectile dysfunction;
- praziquantel; to treat fluke and tapeworms;
- bilastine, ebastine, rupatadine; for allergy;
- reboxetine, venlafaxine; to treat depression and anxiety;
- artemether lumefantrine, 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 Parkinson's Disease;
- cannabinoids; to treat nausea and vomiting, weight loss for patients with immune system problems and muscle spasms in patients with Multiple Sclerosis;
- eletriptan; to treat migraine headaches.
- telithromycin; to treat pneumonia.
- ivacaftor; to treat Cystic Fibrosis.
- galantamine; to treat Alzheimer's disease.
- glecaprevir/pibrentasvir; elbasvir/grazoprevir; ombitasvir/paritaprevir/ritonavir (with or without dasabuvir) combinations, to treat Hepatitis C.
- medicine to treat movements of the mouth, tongue, jaw and sometimes limbs, which cannot be controlled (tardive dyskinesia): valbenazine

If you know you metabolize drugs that are handled/broken down by the enzyme CYP2D6 very quickly,

you should check with your doctor if you can take this medicine as it may require a dose change:

- eliglustat.

Tell your doctor if you are using any of these medicines. This is not a complete list of medicine.

Therefore, tell your doctor about all medicines you take.

How to use SPORANOX®

Always take SPORANOX oral solution without food, because it works better this way.

You are advised not to eat or drink for one hour after taking SPORANOX oral solution.

- How much to use

For the treatment of yeast infections of the mouth or throat:
Two SPORANOX measuring cups per day, taken in 1 intake or divided over 2 intakes, during 1 week. If necessary, your doctor may decide to double the dose or prolong the treatment period.

For the treatment of yeast infections of the foodpipe (esophagus):

One SPORANOX measuring cups per day, for a minimum of 3 weeks. If necessary, your doctor may decide to double the dose or prolong the treatment period.

You should swish the solution around in the mouth for approximately 20 seconds before swallowing it and avoid rinsing after taking it.

For the prevention of fungal infections:

0.5 milliliters of SPORANOX oral solution per kilogram of body weight per day divided over 2 intakes. Your doctor will tell you exactly how much this means for you. Directions for opening the bottle:

The bottle comes with a child-proof cap, and should be opened as follows: push the plastic screw cap down, while turning it



counter
clockwise.

How to use the measuring cup:
Use the measuring cup just as it sits on the bottle. Make sure that the side with the graduations (the side that holds



less) is uppermost; that is the side you have to fill. When the arrow on the side points up, the correct side is uppermost.

- When to use it

Always take SPORANOX exactly as your doctor has told you. You should check with your doctor if you are not sure.

- How long to use it

Continue taking SPORANOX for as long as your doctor recommends.

- If you forget to use it

Take the dose you missed as soon as you remember, and then continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you have missed more than one dose, or are not sure what to do, check with your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

- If you use too much (overdose)

Tell your doctor immediately if you have taken too much SPORANOX oral solution. (S)he will take the necessary measures.

While you are using it

- Things you must do

Always follow your doctor's instructions carefully.

If you have to take SPORANOX Oral Solution continuously for more than 1 month, your doctor may ask you to have your blood checked regularly. This is to make sure that your liver is

not affected.

If there is any chance of you becoming pregnant, talk to your doctor about the need for an adequate contraception. Once you have finished taking SPORANOX Oral Solution, you should continue using adequate contraception until you have had your next period. Tell your doctor immediately if you do become pregnant while taking SPORANOX Oral Solution.

If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking SPORANOX Oral Solution.

Always complete the treatment as directed by your doctor, even if the signs of infection have gone.

- Things you must not do

Do not take SPORANOX Oral Solution to treat any other complaint unless your doctor says so.

Do not give this medicine to anyone else, even if his or her symptoms seem similar to yours.

- Things to be careful of

Driving and using machines

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

Side effects

Like all medicines, SPORANOX can cause side effects, although not everybody gets them. Tell your doctor if you notice any of the following side effects while using SPORANOX:

The following symptoms may occur: upset stomach, nausea, vomiting, diarrhea, abdominal pain, constipation, or excess gas in stomach. Shortness of breath, cough, fluid in the lungs, altered voice, inflammation of the sinuses, inflammation of the nose, upper respiratory tract infection, headache, menstrual

disorder, erectile dysfunction, dizziness, confusion, tremor, sleepiness, fatigue, chills, muscle weakness or pain, painful joints, pain, chest pain, swelling, generalized swelling, inflammation of the pancreas, unpleasant taste, fever, excessive sweating, or hair loss may also occur. In addition, increase in heart rate, increase in blood pressure, decrease in blood pressure, or heart failure may also occur. Changes in laboratory tests may occur such as decrease in granulocytes, decrease in white blood cells, decrease in platelets, decrease in blood magnesium, decrease in blood potassium, increase in blood potassium, increase in blood sugar, increase in blood creatine phosphokinase, increase in liver enzymes, increase in blood bilirubin, increase in blood triglycerides, or increase in blood urea.

- Hypersensitivity to SPORANOX oral solution can occur. It can be recognized, for instance, by skin rash, itching, hives, shortness of breath or difficulty breathing, and/or swollen face. Uncommonly, diminished sensation in the limbs, a tingling sensation in the limbs, or other problems with the nerves in the arms or legs can occur. Very rarely, an oversensitivity to sunlight, or a severe skin disorder (widespread rash with peeling skin and blisters in the mouth, eyes and genitals, or rash with small pustules or blisters) can occur.

- You may experience one or more of the following symptoms that may be related to heart failure: shortness of breath, unexpected weight gain, swelling of the legs, unusual fatigue, or begin to wake up at night.

- One or more of the following symptoms that may be related to liver disorders may appear: lack of appetite, nausea, vomiting, tiredness, abdominal pain, jaundice, very dark urine and pale stools.

- Your vision could get blurry or you could see double. You could hear a ringing in your ears. You could lose the ability to control your urine or urinate much more than usual. You may experience temporary or permanent hearing

loss.

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If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.moh.gov.my [Consumers → Reporting side effects to medicines (ConSERF) or vaccines (AEFI)].

Storage and Disposal of SPORANOX®

- Storage

Keep out of reach and sight of children. This medicine can be kept for only a limited period. Do not use SPORANOX oral solution after the date (month and year) printed after "EXP", even if it has been stored properly.

- Disposal

Return old medicines to your pharmacist.

Product Description

- What it looks like

The solution comes in a 150ml bottle with a measuring cup.

- Ingredients

- Active Ingredients

- The solution also contains caramel flavour, cherry flavour 1 and 2, hydrochloric acid, hydroxypropyl- β -cyclodextrin, propylene glycol, sodium hydroxide, sodium saccharin, sorbitol and water.

- MAL number:

MAL19993011AZ

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