

SPORANOX[®] Oral Solution

Itraconazole

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SPORANOX Oral Solution. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking SPORANOX Oral Solution against the benefits this medicine is expected to have for you.

If you have any concerns about taking SPORANOX Oral Solution, ask your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What SPORANOX Oral Solution is used for

SPORANOX Oral Solution is a medicine used for:

- the treatment of candida (yeast) infections of the mouth, throat and/or gullet in patients who have a lowered resistance to disease.
- the prevention of fungal infections in certain patients who may have a lowered resistance.

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

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.

Before you take SPORANOX Oral Solution

When you must not take it

Do not take SPORANOX Oral Solution if:

- you are pregnant or may become pregnant;
- 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.
- you have an allergy to SPORANOX Oral Solution or any of the ingredients. See Product Description at the end of this leaflet.

Do not take SPORANOX Oral Solution with any of the following:

- terfenadine, astemizole or mizolastine (used for allergy or hayfever);
- bepridil, felodipine, lercanidipine, ivabradine, ranolazine, eplerenone and nisoldipine (used to treat angina (crushing chest pain) or high blood pressure);
- domperidone (used to treat nausea and vomiting);
- ticagrelor (used for the prevention of heart attack or stroke);
- cisapride (used for certain digestive problems);
- certain medicines used to produce calmness or to help you sleep (midazolam (oral) or triazolam);
- simvastatin, lomitapide or lovastatin (used to lower your cholesterol);
- lurasidone, pimozide or sertindole (used to treat mental disorders);
- disopyramide, dronedarone, quinidine or dofetilide (used to treat irregular heartbeats);
- levacetylmethadol, methadone (used for severe pain or to manage opioid-dependency);
- dihydroergotamine and ergotamine (used to treat migraine);

- ergometrine or methylergometrine (used to control bleeding and maintain uterine contraction after child birth);
- halofantrine (used to treat malaria);
- irinotecan, an anti-cancer medicine
- isavuconazole (used to treat fungal infections);
- naloxegol (used to treat constipation caused by taking opioid painkillers);
- avanafil (used to treat erectile dysfunction);
- dapoxetine (used to treat premature ejaculation);
- eliglustat (if you know you do not break down drugs that are broken down by the enzyme known as CYP2D6, you should check with your doctor if you can take this medicine).

If you have kidney or liver problems, do not take SPORANOX capsules with any of the following:

- colchicine (used to treat gout);
- fesoterodine or solifenacin (used to control irritated urinary bladder);
- telithromycin (an antibiotic).

Do not take SPORANOX Oral Solution if the packaging is torn or shows signs of tampering.

Do not take SPORANOX Oral Solution beyond the expiry date (month and year) printed on the pack.

Before you start to take it

You must tell your doctor if:

- you are breast feeding or wish to breastfeed;
- you have had an allergic reaction to other medicines used to treat fungal infections;
- you have or have had any liver problems;
- you have or have had any kidney problems;
- you have a heart problem;
- you suffer from cystic fibrosis.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking or are given SPORANOX Oral Solution.

Your doctor will advise whether or not to take SPORANOX Oral Solution or if you need to adjust the dose or adapt your treatment.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines you can buy without a prescription from a pharmacy, supermarket or health food shop.

In particular, SPORANOX Oral Solution must not be taken with some medicines. Examples are:

- terfenadine, astemizole or mizolastine (used for allergy or hayfever);
- bepridil, felodipine, nisoldipine, lercanidipine, ivabradine, ranolazine, eplerenone (used to treat angina (crushing chest pain) or high blood pressure);
- cisapride (used for certain digestive problems);
- certain medicines used to produce calmness or to help you sleep (midazolam (oral) or triazolam);
- simvastatin, lomitapide or lovastatin (used to lower your cholesterol);
- lurasidone, pimozide or sertindole (used to treat mental disorders);
- disopyramide, dronedarone, quinidine or dofetilide (used to treat irregular heartbeats);
- levacetylmethadol, methadone (used for severe pain and to manage opioid-dependency);
- ticagrelor (used for the prevention of heart attack or stroke);
- dihydroergotamine and ergotamine (used to treat migraine);

- ergometrine or methylergometrine (used to control bleeding and maintain uterine contraction after child birth);
- artemether-lumefantrine, halofantrine, quinine (used to treat malaria);
- irinotecan, an anti-cancer medicine;
- domperidone (used to treat nausea and vomiting);
- isavuconazole (used to treat fungal infections);
- naloxegol (used to treat constipation caused by taking opioid painkillers);
- avanafil (used to treat erectile dysfunction);
- dapoxetine (used to treat premature ejaculation);
- eliglustat (if you know you do not break down drugs that are broken down by the enzyme known as CYP2D6, you should check with your doctor if you can take this medicine).

Medicines that must never be taken while you are taking SPORANOX capsules, if you have kidney or liver problems:

- colchicine (used to treat gout);
- fesoterodine or solifenacin, when used to control irritated urinary bladder;
- telithromycin (an antibiotic).

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

Certain medicines are not recommended because they may be affected by SPORANOX Oral Solution or may affect how well SPORANOX Oral Solution works. Your doctor may need to adjust the dose or adapt your treatment.

Examples of these medicines are:

- phenytoin, phenobarbital or carbamazepine (used to treat fits);
- bedaquiline, delamanid, rifampicin, rifabutin or isoniazid (used to treat tuberculosis);
- certain medicines used to treat HIV/AIDS, such as efavirenz, indinavir, maraviroc, nevirapine, saquinavir and ritonavir, ritonavir-boosted darunavir, ritonavir-boosted fosamprenavir, tenofovir disoproxil fumarate (TDF);
- simeprevir, boosted asunaprevir, boceprevir, daclatasvir, telaprevir, vaniprevir, elbasvir/grazoprevir, glecaprevir / pibrentasvir, ombitasvir /paritaprevir/ritonavir with or without dasabuvir (used to treat hepatitis C);
- certain antineoplastics such as axitinib, bosutinib, bortezomib, brentuximab vedotin, busulphan, carbazitaxel, cabozantinib, ceritinib, cobimetinib, crizotinib, dabrafenib, dasatinib, docetaxel, erlotinib, ibrutinib, idelalisib, ixabepilone, lapatinib, nilotinib, nintedanib, olaparib, panobinostat, pazopanib, ponatinib, regorafenib,

- ruxolitinib, sonidegib, trabectedin, trastuzumab emtansine, vandetanib, vinca alkaloids (used to treat certain cancers);
- sunitinib (used to treat certain types of stomach, bowel, or esophagus tumor and kidney or pancreatic cancer);
 - gefitinib (used to treat breast, lung and other cancers);
 - imatinib (used to treat lung cancer);
 - aliskiren, diltiazem (to treat hypertension);
 - bosentan, digoxin, nadolol, riociguat, and certain calcium channel blockers including amlodpine besylate, nifedipine, nimodipine, other dihydropyridines and verapamil (used to treat heart or blood pressure problems);
 - vorapaxar (used to treat heart attacks or strokes);
 - atorvastatin (used to lower cholesterol);
 - anticoagulants such as apixaban, coumarins & coumarin-like medicines (e.g. warfarin), cilostazol, dabigatran, rivaroxaban (used to slow blood clotting);
 - alfuzosin, dutasteride, soldosin (used to treat Benign Prostatic enlargement);
 - sildenafil (used to treat erectile dysfunction or pulmonary hypertension);
 - tadalafil, udenafil, vardenafil (used to treat erectile dysfunction);

- colchicine (used to treat gout);
- conivaptan, tolvaptan (used to treat low blood sodium levels);
- mozavaptan; to treat low blood sodium;
- fentanyl, a strong medicine for pain;
- alfentanil, buprenorphine, oxycodone, sufentanil (used in surgery for pain relief and to help anaesthesia);
- meloxicam, to treat joint inflammation and pain;
- salmeterol (to improve breathing)
- darifenacin, fesoterodine, imidafenacin, oxybutynin, tolterodine (used to treat urinary incontinence);
- tamsulosin (used to treat male urinary incontinence)
- ciprofloxacin, clarithromycin, erythromycin, telithromycin (antibiotics);
- methylprednisolone, budesonide, ciclesonide, fluticasone and dexamethasone (often used for conditions such as inflammations, asthma and allergies);
- bilastine, ebastine, rupatadine (used to treat allergies);
- everolimus (given after an organ transplant)
- cyclosporin, rapamycin (also known as sirolimus), tacrolimus, temsirolimus (used to help prevent organ

transplant rejection or to treat certain problems with the immune system);

- trimetrexate (used to treat certain type of pneumonia);
- buspirone, perospirone, ramelteon, midazolam IV, alprazolam, brotizolam (used to treat anxiety or help you sleep);
- aripiprazole, cariprazine, haloperidol, quetiapine, risperidone to treat psychosis;
- medicines taken for diabetes (in particular repaglinide and saxagliptin);
- aprepitant, netupitant (used for nausea and vomiting during cancer treatment)
- praziquantel, (used to treat fluke and tapeworms);
- some contraceptive pills (birth control pills), such as dienogest, ulipristal;
- reboxetine, venlafaxine (used to treat depression and anxiety);
- cinacalcet, to treat an over active parathyroid;
- alitretinoin (oral formulation), to treat eczema;
- eletriptan (used to treat migraine);
- *Saccharomyces boulardii*, loperamide (used to treat diarrhea);

- lumacaftor/ ivacaftor (used to treat Cystic Fibrosis);
- guanfacine (used to treat Attention Deficit Hyperactivity Disorder);
- suvorexant, zopiclone (used to treat insomnia);
- 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;
- galantamine (used to treat Alzheimer's disease).

Taking SPORANOX Oral Solution

How much to take

Adults

The usual doses are shown below, but your doctor may decide to adjust them to your individual needs:

Treatment of yeast infections in the mouth, throat or gullet

- one (100 mg or 10 mL) or two measuring cups (200 mg or 20 mL) once a day or
- one measuring cup (100 mg or 10 mL) twice a day (morning and afternoon).
- a measuring cup is supplied with the product.

- SPORANOX Oral Solution is usually taken for one to five weeks.
- Your doctor or healthcare professional may prescribe a different dose or treatment duration of SPORANOX Oral Solution. Take this medicine exactly as prescribed for you.

Prevention of fungal infections

- the dose will depend on your body weight. Your doctor will tell you how much and how often you should take SPORANOX Oral Solution.
- SPORANOX Oral Solution is usually taken up to 8 weeks.

Children and Elderly

Sporanox Oral Solution is not recommended for use in children and in the elderly.

How to take it

- You should always take SPORANOX Oral Solution on an empty stomach, at least one hour before a meal.
- If you are taking SPORANOX Oral Solution for the treatment of yeast infections in the mouth or throat, you should swish the solution around the mouth for about 20 seconds before swallowing. **DO NOT RINSE** your mouth after swallowing.

Directions for opening the bottle

The bottle comes with a child-resistant cap, and should be opened by pushing the plastic screw cap down while turning it anti-clockwise.

If you forget to take 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 have taken too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre for advice, or go to Accident and Emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Poisons Information Centre telephone numbers:

- Australia: 13 11 26
- New Zealand: 0800 POISON or 0800 764 766

Keep these telephone numbers handy.

While you are taking SPORANOX Oral Solution

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 highly effective contraception. Once you have finished taking SPORANOX Oral Solution, you should continue using highly effective 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

Be careful driving or operating machinery.

You may feel dizzy while taking SPORANOX Oral Solution. If you experience this or similar effects, you should avoid driving and using machines.

Make sure you know how you react to SPORANOX Oral Solution before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or lightheaded.

Side Effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some side effects. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you experience any of the following:

- upset stomach, stomach cramps, nausea, vomiting, diarrhoea, constipation, an unpleasant taste in your mouth.
- shortness of breath, headache, dizziness, fever.
- cough, chills, cold or flu-like symptoms
- a change in menstrual pattern.
- unusual hair loss or thinning.
- erectile dysfunction.
- muscle weakness or pain, painful joints.
- inflammation of the pancreas.

Tell your doctor immediately if you notice any of the following as you may need urgent medical care:

- tingling, numbness or weakness in the hands or feet.
- increased heart rate
- swelling of hands, ankles, feet, the legs or the abdomen.
- shortness of breath, unexpected weight gain, unusual fatigue, or begin to wake up at night.
- oversensitivity to sunlight.
- blurry or double vision, ringing in the ears.
- lose the ability to control your bladder or urinate much more than usual.

STOP taking SPORANOX Oral Solution and tell your doctor immediately or go to Accident and Emergency at your nearest hospital if any of the following happen:

- abnormal tiredness, loss of appetite, nausea, vomiting, dark urine, pale stools, yellowing of the skin or eyes.
- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.
- a severe skin disorder (widespread rashes with peeling skin and blisters in the mouth, eyes and genitals, or rashes with small pustules or blisters).
- you experience any hearing loss symptoms. In very rare cases, patients taking SPORANOX have reported temporary or permanent hearing loss.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

After taking SPORANOX Oral Solution

Storage

- Keep SPORANOX Oral Solution in the bottle until it is time to take it.
- Keep your SPORANOX Oral Solution in a cool, dry place where the temperature is below 25°C.

- Keep your medicines where children cannot reach it. A locked cupboard at least one-and-a-half metres (1.5 m) above the ground is a good place to store medicines.
- Do not store SPORANOX Oral Solution, or any medicine, in the bathroom or near a sink. Do not leave medicines in the car or on window sills. Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking SPORANOX Oral Solution, or your medicine has passed its expiry date, ask your pharmacist what to do with any medicine which may be left over.

Product Description

What it looks like

SPORANOX Oral Solution is a yellow to slightly amber clear solution.

It is supplied in 150 mL amber glass bottle with a child-resistant screw cap. A 10 mL measuring cup is provided in the pack.

Ingredients

The active ingredient in SPORANOX Oral Solution is 100 mg/10 mL of itraconazole.

Other ingredients include hydroxypropylbetadex, sorbitol solution (70%, non-crystallising), propylene glycol,

hydrochloric acid, 654536 cherry flavour , 654595 cherry flavour , caramel flavour, saccharin sodium, sodium hydroxide and purified water.

SPORANOX Oral Solution contains saccharin.

SPORANOX Oral Solution does not contain lactose or gluten.

Sponsor

JANSSEN-CILAG Pty Ltd

1-5 Khartoum Road

Macquarie Park NSW 2113 Australia

Telephone: 1800 226 334

NZ Office: Auckland New Zealand

Telephone: (09) 523 8700 or 0800 800 806

Australian Registration Number: AUST R 62008

This leaflet was prepared in June 2021.