

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only

**Name of the medicine, its form and strength:**

**Sporanox® Oral Solution, 10 mg/ml**

**Active ingredient and its concentration:**

Each 1 ml contains 10 mg itraconazole

Inactive and allergenic ingredients in the preparation – see section 6 “Further information” and section 2 “Important information about some of the ingredients in this medicine”.

**Read the leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

**1. WHAT IS THE MEDICINE INTENDED FOR?**

Sporanox Oral Solution is one of a group of medicines called antifungals. These medicines are used to treat and prevent infections caused by fungi, including yeasts. The medicine is used to treat fungal infections of the throat and gullet and prevent fungal infections in states of neutropenia in patients with impaired immune system function.

**Therapeutic group:** triazole antifungals.

**2. BEFORE USING THE MEDICINE**

**Do not use the medicine if:**

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine listed in section 6 (“Further information”).
- You are pregnant, think you might be pregnant or could become pregnant (see Pregnancy section).

Before using Sporanox Oral Solution, tell your doctor if you are taking any medicines.

• **Do not use Sporanox Oral Solution** if you are taking any of the following medicines. If you are using Sporanox Oral Solution and you must start using one of the medicines listed below, start this treatment 2 weeks after stopping Sporanox Oral Solution.

- **Medicines to treat problems with the heart, blood or circulation**
  - aliskiren, eplerenone, lercanidipine or nisoldipine (for high blood pressure)
  - bepridil, ivabradine or ranolazine (for angina)
  - dabigatran or ticagrelor (for blood clots)
  - disopyramide, dofetilide, dronedarone or quinidine (for irregular heart rhythm)
  - lomitapide, lovastatin or simvastatin (to lower cholesterol)
  - sildenafil (for pulmonary hypertension)
- **Medicines to treat stomach hypochloric acid or constipation**
  - cisapride (for stomach pain)
  - domperidone (for nausea or vomiting)
  - naloxegol (for constipation caused by taking opioid painkillers)
- **Medicines to treat headaches, sleep or mental health problems**
  - dihydroergotamine or ergotamine (ergot alkaloids used to treat migraine headaches)
  - midazolam (taken by mouth) or triazolam (for sedation or to help you sleep)
  - lurasidone, pimozide, quetiapine or sertindole (for schizophrenia, bipolar disorder or other mental health problems)
- **Medicines to treat problems passing urine**
  - darifenacin (for urinary incontinence)
  - fesoterodine or solifenacin (for irritated urinary bladder) when used in patients with certain kidney or liver problems
- **Medicines to treat allergies**
  - astemizole, mizolastine or terfenadine (for allergies)
- **Medicines to treat erection and ejaculation problems**
  - avanafil (for erection problems)
  - dapoxetine (for premature ejaculation)
  - vardenafil (for erection problems) when used in men older than 75 years of age
- **Other medicines containing:**
  - colchicine (for gout) when used in patients with kidney or liver problems
  - ergometrine (ergonovine) or methylergometrine (methylergonovine) – ergot alkaloids used after giving birth
  - eliglustat (for Gaucher's disease) when used in patients whose body cannot break down certain medicines
  - halofantrine (for malaria)
  - irinotecan (for cancer)
  - isavuconazole (for fungal infections)
  - ombitasvir, paritaprevir, ritonavir with or without dasabuvir (to treat hepatitis C)

**Remember – do not take any of the medicines listed above for 2 weeks after the last treatment with Sporanox Oral Solution.**

**Special warnings regarding use of the medicine Before starting treatment with Sporanox Oral Solution, tell the doctor if:**

**Stop taking Sporanox Oral Solution** and refer to your doctor immediately if you experience any of the following symptoms of severe liver problems during the course of treatment:

- Severe lack of appetite, feeling sick, being sick, unusual tiredness, abdominal pain, unusually dark urine or pale stools.

**Tell your doctor immediately:**

- If you develop any unusual feelings of tingling, reduced sensation or weakness in the hands or legs whilst taking Sporanox Oral Solution.
- If you experienced hearing loss symptoms. In very rare cases, patients taking Sporanox Oral Solution reported temporary or permanent hearing loss.

**Tell your doctor if you have:**

- had an allergic reaction to other antifungal medicines.
- a heart problem, including heart failure. Sporanox Oral Solution could worsen your condition. If your doctor decides to give you Sporanox Oral Solution, you must be aware of and look out for the following symptoms. If you notice any of them, stop taking Sporanox Oral Solution and tell the doctor immediately. These may be signs of heart failure:
  - shortness of breath
  - unexpected weight gain
  - swelling of the legs or stomach
  - unusual tiredness
  - if you wake up short of breath at night
- liver problems, such as jaundice (yellowing of the skin); the dosage of Sporanox Oral Solution may have to be changed. The doctor should instruct you on symptoms you should watch out for. If you have to take Sporanox Oral Solution for a prolonged period, for more than one month, the doctor may want to check your liver by doing blood tests. In addition, there may be specific medicines you will not be able to take.
- cystic fibrosis (a hereditary disease affecting the lungs, pancreas, liver, kidneys and intestines).
- kidney problems, as the dosage of Sporanox Oral Solution may have to be changed. In addition, there may be specific medicines you will not be able to take.

**Children**

Sporanox Oral Solution is not usually intended for children. The doctor may have to prescribe it in special cases.

Sporanox Oral Solution contains cyclodextrin, propylene glycol and alcohol (ethanol). Do not use in children under two years of age, unless the doctor has recommended its use. If your child is under 5 years of age, consult the doctor or pharmacist before administering the medicine, especially if the child is receiving other medicines that contain cyclodextrin, propylene glycol or alcohol.

**Drug interactions**

**If you are taking, may take, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist,** especially if you are taking:

**Certain medicines should not be taken together with Sporanox Oral Solution.** These medicines are listed under “Do not use the medicine if”.

**Certain medicines are not recommended for use together with Sporanox Oral Solution.** The doctor may decide that you cannot take some of the medicines at the same time as, or within 2 weeks of stopping Sporanox Oral Solution.

Examples of these medicines are:

- **Medicines to treat problems with the heart, blood or circulation**
  - apixaban, rivaroxaban or vorapaxar (for blood clots)
  - atorvastatin (to lower cholesterol level)
  - felodipine (for high blood pressure)
  - riociguat or tadalafil (for pulmonary hypertension)
- **Medicines to treat epilepsy, headaches or mental health problems**
  - phenytoin, carbamazepine or phenobarbital (anti-epileptics)
  - eletriptan (for migraine headaches)
  - St. John's wort (*Hypericum perforatum*) (a herbal medicine to treat mental health problems)
- **Medicines to treat problems passing urine**
  - tamsulosin (for male urinary incontinence)
  - tolterodine (for irritated urinary bladder)
- **Medicines to treat cancer**
  - axitinib, bosutinib, cabazitaxel, cabozantinib, ceritinib, cobimetinib, crizotinib, dabrafenib, dasatinib, docetaxel, ibrutinib, lapatinib, nilotinib, olaparib, pazopanib, regorafenib, sunitinib, trabectedin, trastuzumab emtansine, or vinca alkaloids (e.g., vinflunine or vinorelbine)
- **Medicines to treat tuberculosis**
  - bedaquiline, isoniazid, rifabutin or rifampicin (for tuberculosis)
- **Medicines to treat HIV or hepatitis**
  - efavirenz or nevirapine (medicines to treat HIV/AIDS)
  - elbasvir/grazoprevir, simeprevir, tenofovir alafenamide fumarate (TAF), tenofovir disoproxil fumarate (TDF) (to treat HIV or hepatitis)
- **Medicines given after organ transplant**
  - everolimus, rapamycin (also known as sirolimus) or temsirolimus
- **Medicines to treat benign prostatic enlargement**
  - alfuzosin, silodosin
- **Medicines to treat lung problems or allergies**
  - ciclosporine (for inflammation, asthma and allergies)
  - ebastine (for allergies)
  - salmeterol (for asthma or chronic obstructive pulmonary disease – COPD)
- **Medicines to treat erection and ejaculation problems**
  - tadalafil or vardenafil (when used in men 75 years of age and younger) (for erection problems)
- **Other medicines**
  - colchicine (for gout)
  - fentanyl (for pain)
  - lumacaftor/ivacaftor (for cystic fibrosis)

**Remember – do not take any of the medicines above for 2 weeks after the last treatment with Sporanox Oral Solution.**

This is not the complete list, so tell your doctor if, or any other medicine.

**Care needs to be taken when using Sporanox Oral Solution with certain other medicines.** The likelihood of side effects may increase, or the dosage of Sporanox Oral Solution or the other medicines might need to be changed. Examples of these medicines are:

- **Medicines to treat problems with the heart, blood or circulation**
  - bosentan (for pulmonary hypertension)
  - calcium channel blockers such as dihydropyridines such as amlodipine, isradipine, nifedipine, nimodipine or diltiazem (for hypertension)
  - or verapamil (for high blood pressure)
  - cilostazol (for circulatory problems)
  - 'coumarins' (such as warfarin) (for blood clots)
  - digoxin (for atrial fibrillation)
  - nadolol (for pulmonary hypertension or angina)
- **Medicines to treat stomach problems or diarrhea**
  - aprepitant or netupitant (for nausea and vomiting during cancer treatment)
  - loperamide (to treat diarrhea)
  - antacids such as aluminum, calcium, magnesium, sodium bicarbonate, H<sub>2</sub>-receptor antagonists such as cimetidine, ranitidine, and proton pump inhibitors such as lansoprazole, omeprazole, rabeprazole (to treat stomach acid problems)
- **Medicines to treat sleep problems or mental health problems**
  - alprazolam, brotizolam, buspirone or midazolam (when injected into a vein) (for anxiety or to help you sleep)
  - zopiclone (to help you sleep)
  - reboxetine or venlafaxine (for depression and anxiety)
  - aripiprazole, cariprazole, haloperidol or risperidone (for schizophrenia, bipolar disorder or other mental health problems)
  - galantamine (for Alzheimer's disease)
  - guanfacine (for attention deficit hyperactivity disorder)
- **Medicines to treat problems passing urine**
  - imidafenacin, fesoterodine, oxybutynin, solifenacin (for irritated urinary bladder)
- **Medicines to treat cancer**
  - bortezomib, brentuximab vedotin busulfan, erlotinib, gefitinib, idelalisib, imatinib, nintedanib, panobinostat, ponatinib, ruxolitinib or sunitinib
- **Medicines to treat infections**
  - ciprofloxacin, clarithromycin or erythromycin (for bacterial infections)
  - delamanid (for tuberculosis)
  - artemether-lumefantrine or quinidine (to treat malaria)
  - praziquantel (for fluke and tapeworms)
- **Medicines to treat HIV or hepatitis**
  - cobicistat, boosted elvitegravir, maraviroc, ritonavir, ritonavir-boosted darunavir, ritonavir-boosted fosamprenavir, indinavir or saquinavir (for HIV)
  - glecaprevir/pibrentasvir (for hepatitis)
- **Medicines used after organ transplant**
  - ciclosporine or tacrolimus
- **Medicines to treat benign prostatic enlargement**
  - dutasteride
- **Medicines to treat lung problems, allergies or inflammatory conditions**
  - bilastine or rupatadine (for allergy)
  - methylprednisolone or dexamethasone (medicines given by mouth or injection for asthma, allergy or inflammatory conditions)
  - budesonide or fluticasone (for asthma, allergy)
- **Medicines to treat erection and ejaculation problems**
  - sildenafil (for erection problems)

**• Medicines to treat pain**

- alfentanil, buprenorphine, oxycodone or sufentanil (for pain)
- meloxicam (for joint inflammation and pain)

**• Other medicines**

- alitretinoin (given by mouth) (for eczema)
- cabergoline (for Parkinson's disease)
- cannabis-based products including medicines (for nausea and vomiting or muscle spasms in patients with multiple sclerosis)
- cinacalcet (for an overactive thyroid)
- dienogest or ulipristal (contraceptives)
- eliglustat (for Gaucher's disease), used in patients whose body cannot break down certain medicines
- ivacaftor (for cystic fibrosis)
- methadone (to treat drug addiction)
- repaglinide or saxagliptin (for diabetes)

This is not a complete list, so tell the doctor if you are taking or planning to take any of these medicines, or any other medicine.

**Use of the medicine with food**

Do not take Sporanox Oral Solution together with food or a drink, as it reduces the ability of the body to absorb the medicine. Always take Sporanox Oral Solution one hour before eating or drinking to help the body absorb the medicine.

**Elderly**

Sporanox Oral Solution is not usually intended for the elderly. The doctor may prescribe it in special cases.

**Pregnancy**

Do not take Sporanox Oral Solution if you are pregnant, unless instructed to do so by the doctor.

If you are of child-bearing age and could become pregnant, consult a doctor. Use effective contraceptives to make sure that you do not become pregnant while you are taking this medicine. As Sporanox Oral Solution remains in the body for some time after you stop taking it, continue to use some form of contraception until your next period after treatment is discontinued.

If you discover that you are pregnant after starting treatment with Sporanox Oral Solution, stop the treatment and tell the doctor immediately.

Before you take any medicine, always tell the doctor if you are pregnant, think you might be pregnant or are trying to become pregnant.

**Breastfeeding**

If you are breastfeeding, do not take Sporanox Oral Solution, as small amounts of the medicine could be present in breast milk. If the doctor recommends taking Sporanox Oral Solution, they may carry out additional tests during the course of treatment with the medicine.

**Driving and operating machinery**

Sporanox Oral Solution may sometimes cause dizziness, blurred/double vision or hearing loss. If you have these symptoms, do not drive and do not operate machinery.

**Important information about some of the ingredients in this medicine**

**Sporanox Oral Solution contains sorbitol**

The medicine contains 7,920 mg sorbitol per 40 ml dose, which is equivalent to 198 mg per ml.

If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance, a rare genetic disorder in which there is an inability to break down fructose, consult the doctor before you (or your child) use the medicine. Sorbitol is a source of fructose and may cause gastrointestinal discomfort and a mild laxative effect.

**Sporanox Oral Solution contains propylene glycol**

This medicine contains 4.2 g propylene glycol in each 40 ml dose, which is equivalent to 104 mg/ml. If you are pregnant, breastfeeding or suffer from a liver or kidney disease, do not take this medicine unless recommended by the doctor. Your doctor may carry out additional tests while you are taking this medicine.

**Sporanox Oral Solution contains cyclodextrin**

This medicine contains 16,000 mg cyclodextrin in each 40 ml dose, which is equivalent to 400 mg/ml. Cyclodextrin may cause digestive problems such as diarrhea.

**Sporanox Oral Solution contains alcohol (ethanol)**

This medicine contains 0.2 mg alcohol (ethanol) in each 40 ml dose, which is equivalent to 0.005 mg/ml.

This amount in 40 ml of this medicine is equivalent to less than 1 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effect.

**Sporanox Oral Solution contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per 40 ml, that is to say, it is essentially “sodium-free”.

**3. HOW SHOULD THE MEDICINE BE USED?**

Always take Sporanox Oral Solution one hour before eating or drinking, to help the body absorb the medicine. Gargle the medicine in the mouth for approximately 20 seconds before swallowing. Do not rinse the mouth after swallowing the oral solution.

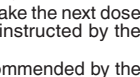
Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

A measuring cup graduated to indicate 10 ml is provided. Ensure you fill the cup to the 10 ml mark. The dosage and treatment regimen will be determined by the doctor only.

**Do not exceed the recommended dosage.**

**Directions for opening the bottle:**

The bottle has a child-proof cap. Open the bottle by pushing the cap down (1) while turning it counter-clockwise (2).



**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 narrower side) is upward; that is the side you have to fill. When the arrow on the side points up, the correct side is facing up.

**If you accidentally took a higher dosage** or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

**If you forgot to take the medicine,** take the next dose as usual and continue treatment as instructed by the doctor. Do not take a double dose.

Adhere to the treatment regimen recommended by the doctor. Even if there is an improvement in your condition, do not stop taking the medicine without consulting the doctor.

**Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.**

**If you have further questions regarding use of the medicine, consult the doctor or pharmacist.**

**4. SIDE EFFECTS**

As with any medicine, use of Sporanox Oral Solution may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Medicines can cause serious allergic reactions.

**Stop taking the medicine and contact the doctor immediately if you have:**

- sudden wheeziness, difficulty breathing, swelling of the face, rash, itching (affecting the whole body) or a severe skin problem (widespread rashes with peeling skin and blisters in the mouth, eyes and genitals or rashes with small pustules or blisters).
- severe lack of appetite, feeling sick, being sick, unusual tiredness, abdominal pains, unusually dark urine, or pale stools. These may be symptoms of severe liver problems.

In addition, refer to a doctor immediately if you suffer from the following side effects:

- Symptoms that resemble heart failure, such as shortness of breath, unexpected weight gain, swelling of the legs, unusual fatigue or repeated waking at night.
- A tingling sensation, sensitivity to light, numbness or weakness in the limbs.
- Blurred/double vision, ringing in the ears, loss of the ability to control urine or increased frequency of urination (pass water).
- If you experience hearing loss symptoms.
- Severe upper stomach pain, usually with nausea and vomiting due to inflammation of the pancreas (pancreatitis).

Other side effects include:

Common side effects – effects that occur in 1-10 in 100 users:

- headache
- stomachache, nausea, vomiting, diarrhea, indigestion, unpleasant taste
- rash
- fever or high temperature
- shortness of breath
- dizziness
- cough

Uncommon side effects – effects that occur in 1-10 in 1,000 users:

- certain blood disorders which may increase the risk of bleeding or bruising (possible symptoms of a low level of platelets), or infections (possible symptoms of a low level of white blood cells)
- constipation
- itching, hives
- general swelling
- muscle cramps or irregular heart rate (possible symptoms of low blood potassium level)
- muscle pains, painful joints
- abnormal menstrual bleeding
- decreased feeling or sensitivity, especially in the skin

Side effects of unknown frequency (effects whose frequencies have not been determined) that have been reported by patients who took Sporanox Oral Solution:

- excess triglycerides (fats) in the blood
- hair loss
- increase in blood creatinine phosphokinase levels

The following side effects have been reported in patients who took other formulations of Sporanox Oral Solution:

- infection of the upper respiratory tracts
- inflammation of the nose
- inflammation of the sinuses
- a blood problem which may increase the risk of infections (a possible symptom of low levels of granulocytes)
- high blood sugar level
- muscle cramps or irregular heart rate (possible symptoms of low blood magnesium level)
- muscle cramps or irregular heart rate (possible symptoms of high blood potassium level)

- confusion
- sleepiness
- tremors
- increase in heart rate
- high blood pressure
- low blood pressure
- fluid in the lungs
- difficulty speaking
- excess gas in the intestinal tract
- increases in liver function in specific tests (hepatic enzymes increased)
- inflammation of the liver (hepatitis)
- yellowing of the skin (jaundice)
- increased sweating
- kidney problems
- increased urine production
- erection problems
- general swelling
- facial swelling
- chest pain
- pain
- chills
- fatigue
- increase in blood urea levels
- abnormal urine findings

**If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.**

Side effects can be reported to the Ministry of Health by clicking on the link “Reporting Side Effects of Drug Treatment” found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

**5. HOW SHOULD THE MEDICINE BE STORED?**

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use the medicine after the expiry date (Exp. Date) that appears on the package/bottle. The expiry date refers to the last day of that month.

Store at a temperature of 25°C or below. Do not use the oral solution for more than one month after first opening.

**6. FURTHER INFORMATION**

In addition to the active ingredient, the medicine also contains:

Hydroxypropyl-β-cyclodextrin, sodium saccharin, cherry flavor 2, cherry flavor 1, caramel, sorbitol liquid non-crystallising, propylene glycol, concentrated hydrochloric acid, sodium hydroxide, purified water.

What the medicine looks like and the contents of the package:

The solution is clear, yellow to slightly yellowish-brown, with a cherry scent.

Sporanox Oral Solution comes in a 150 ml bottle, together with a measuring cup.

Importer, Registration Holder and Address: J-C Health Care Ltd., Kibbutz Shefayim 6099000, Israel.

This leaflet was revised in 08-2021.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 141 49 29632 01