

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

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### **Sporanox 10mg/ml Oral Solution**

(itraconazole)

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**Read all of this leaflet carefully before you start taking your medicine:**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if their symptoms are the same as yours.
- 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.

**In this leaflet:**

- 1. What Sporanox oral solution is and what it is used for**
- 2. Before you use Sporanox oral solution**
- 3. How to use Sporanox oral solution**
- 4. Possible side effects**
- 5. How to store Sporanox oral solution**
- 6. Further information**

## **1. What Sporanox oral solution is and what it is used for**

Sporanox is one of a group of medicines called “antifungals”. These medicines are used to treat and stop you from getting infections caused by fungi including yeasts.

You may be given Sporanox to:

- treat yeast infections of the mouth, throat or gullet if you have a poor immune system
- stop you from getting certain fungal infections if you have a poor immune system due to a major blood disorder or bone marrow transplantation.

## **2. Before you use Sporanox oral solution**

**Do not use Sporanox oral solution if you are:**

- **allergic** (hypersensitive) to itraconazole or to any of the ingredients in Sporanox oral solution (listed in Section 6 Further information)
- **pregnant**, think you might be pregnant or could become pregnant (see the section on Pregnancy)
- taking any of the following medicines:
  - terfenadine, astemizole or mizolastine (antihistamine for allergies)
  - bepridil- used to treat angina (crushing chest pain)
  - nisoldipine (used for high blood pressure)
  - cisapride (used for stomach upsets)
  - midazolam by mouth or triazolam (used to help you sleep or for anxiety)
  - lovastatin, simvastatin or atorvastatin (used to lower cholesterol)
  - pimozide and sertindole (for conditions affecting thoughts, feelings and/or behaviour)
  - levacetylmethadol- for treatment of drug abuse (opioid-dependency)

- dihydroergotamine, ergotamine and eletriptan (for migraine headaches)
- ergometrine (ergonovine) and methylergometrine (methylergonovine) used after giving birth
- quinidine and dofetilide (for irregular heart beat rhythms).

### **Take special care with Sporanox oral solution**

**Stop taking Sporanox** and see your doctor immediately if any of the following symptoms of severe liver problems appear during your course of treatment:

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

### **Tell your doctor immediately:**

- If you have any unusual feelings of tingling, numbness or weakness in your hands or feet whilst taking Sporanox.
- 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 you have:**

- had an allergic reaction to any other antifungal medicines
- a heart problem, including heart failure (also called congestive heart failure or CHF), Sporanox could make it worse. If your doctor decides to give you Sporanox, you should be told about the symptoms listed below to watch out for. If you get any of the following stop taking Sporanox *and* tell your doctor straight away. These may be signs of heart failure:
  - shortness of breath
  - unexpected weight gain
  - swelling of your legs or stomach
  - feel unusually tired
  - wake up short of breath at night
- a liver problem, such as jaundice (yellowing of the skin) as your dose of Sporanox may have to be changed. Your doctor should give you instructions on symptoms to watch out for. If you have to take Sporanox continuously for more than one month, your doctor may want to check your liver by doing blood tests
- a kidney disorder as your dose of Sporanox may have to be changed

### **Taking other medicines**

There are some medicines that **you should not take** whilst taking Sporanox. These are listed under the heading “**Do not use Sporanox oral solution if you are:**”

**Tell your doctor if you are using** the following medicines as they may stop Sporanox oral solution from working properly:

- rifampicin, rifabutin and isoniazid (antibiotics used for tuberculosis)
- phenytoin, carbamazepine and phenobarbital (anti-epileptics)
- St. John's wort

Do not use Sporanox oral solution within 2 weeks of taking these medicines.

**Tell your doctor before taking** any of the following medicines as the dose of **Sporanox** oral solution or other treatments may need to be altered:

- clarithromycin and erythromycin (antibiotics for infections)
- medicines that act on the heart and blood vessels (digoxin, disopyramide and calcium channel-blockers such as dihydropyridines, verapamil and cilostazol)
- drugs that slow down blood clotting or thin the blood, such as warfarin
- methylprednisolone, budesonide, fluticasone and dexamethasone, medicines given by mouth and injection for inflammation, asthma and allergies
- ciclosporin, tacrolimus and rapamycin (also known as sirolimus), which are usually given after an organ transplant
- medicines used in HIV-infected patients, such as ritonavir, indinavir and saquinavir
- medicines for cancer (such as busulphan, docetaxel, trimetrexate and a group of medicines known as vinca alkaloids)
- alfentanil and fentanyl (for pain)
- buspirone, alprazolam, brotizolam and midazolam when given by injection into a vein (for anxiety or to help you sleep)
- reboxetine (for depression)
- loperamide (for diarrhoea)
- an antihistamine containing ebastine
- halofantrine (for malaria)
- repaglinide (for diabetes)

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

### **Using Sporanox oral solution with food and drink**

Do not take Sporanox with food or drink as it reduces your body's ability to absorb the medicine. Always take Sporanox oral solution one hour before any food or drink as this helps the body absorb the medicine.

### **Children and the elderly**

Sporanox is not normally given to children or the elderly. Your doctor may prescribe it in special cases.

### **Pregnancy**

Do not take Sporanox if you are pregnant, unless your doctor has told you to. If you are of child bearing age and could become pregnant, you should use contraceptives 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 has finished.

If you do find that you are pregnant after starting a course of Sporanox, stop taking it and tell your doctor straight away.

Before taking any medicine - always tell your doctor if you are pregnant, think you might be pregnant or are trying to become pregnant.

**Breast feeding**

If you are breast-feeding do not take Sporanox, as small amounts of the medicine could be present in your breast milk.

**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.

**Important information about some of the ingredients of Sporanox oral solution**

Tell your doctor if you are intolerant to fructose (a type of sugar) as this is in sorbitol, one of the ingredients of Sporanox oral solution.

**3. How to use Sporanox oral solution**

Always take Sporanox oral solution one hour before any food or drink as this helps the body absorb the medicine.

You should swish the oral solution around in your mouth for approximately 20 seconds before swallowing it. Do not rinse your mouth after swallowing the oral solution.

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

A measuring cup graduated to indicate 10ml is provided. Ensure you fill the cup to the 10ml mark.

**How to take Sporanox oral solution**

- **Treatment of yeast infections of the mouth, throat or gullet**

The usual dose is 2 measuring cups (20ml) per day for one week. This may be taken either all at once or in two divided doses during the day.

If after one week of using Sporanox, your infection has not cleared, your doctor may decide to continue your treatment for one more week.

- **Treatment of yeast infections of the mouth, throat or gullet, that have already been treated with another antifungal but have still not cleared**

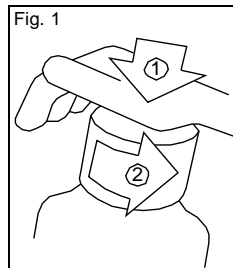
The usual dose is 1-2 measuring cups (10-20 ml) twice daily for two weeks. The treatment may be continued for an additional two weeks, if the infection does not clear in the initial two weeks of treatment. For patients on the higher dose of 400mg (4 measuring cups) daily, treatment should be limited to 14 days, if there are no signs of improvement during this time.

- **Prevention of fungal infections**

The dose is calculated according to your body weight (5 mg per kg) given in two divided doses. Your doctor will tell you exactly how much you should take.

**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.



### **If you take too much Sporanox oral solution**

If you, or anyone else, take more Sporanox than you were told to, contact your doctor or local hospital without delay.

### **If you forget to take Sporanox oral solution**

If you forget to take your medicine, take the next dose as usual and continue your medicine as directed by your doctor. Do not take a double dose.

If you have any further questions on the use of Sporanox, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, Sporanox oral solution can cause side effects, although not everybody gets them.

Medicines can cause serious allergic reactions. **Stop taking Sporanox and contact your doctor immediately** if you have:

- any sudden wheeziness, difficulty in breathing, swelling of the face, rash, itching (especially affecting the whole body) or a severe skin disorder (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 (stomach) pain, unusually dark urine, or pale stools. These may be symptoms of severe liver problems.

You should also let your doctor know immediately if you have any of the side effects below:

- Symptoms that resemble heart failure such as shortness of breath, unexpected weight gain, swelling of the legs, unusual fatigue (tiredness), repeated waking at night.
- A tingling sensation, sensitivity to light, numbness or weakness in the limbs.
- Blurred vision/double vision, ringing in your ears, lose the ability to control your urine or increased need to urinate (pass water)
- If you experience any hearing loss symptoms

Other side effects include:

**Common** side effects (occur in less than 1 in 10 patients) are:

- headache
- stomach ache, feeling sick (nausea), being sick (vomiting), diarrhoea, unpleasant taste
- increases in specific liver function tests (hepatic enzyme increased)
- rash
- fever or high temperature
- shortness of breath

**Uncommon** side effects (occur in less than 1 in 100 patients) are:

- certain blood disorders which may increase the risk of bleeding, bruising or infections
- muscle weakness (possible symptom of low blood levels of potassium)
- dizziness
- indigestion, constipation
- inflammation of the liver (hepatitis), yellowing of the skin (jaundice)
- itching
- general swelling

The following side effects have been reported in patients taking Sporanox with unknown frequency:

- excess of triglycerides in the blood
- hair loss
- muscle pain, painful joints
- menstrual disorders
- erectile dysfunction
- severe upper stomach pain, often with nausea and vomiting due to inflammation of the pancreas (pancreatitis)

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

## **5. How to store Sporanox oral solution**

Keep out of the reach and sight of children.

Do not store Sporanox oral solution above 25°C.

Do not use the Sporanox oral solution after the expiry date printed on the packaging. The expiry date refers to the last day of that month.

The oral solution should not be used for longer than 1 month after the bottle has first been opened.

Always return any left over medicine to your pharmacist. Only keep it if your doctor tells you to.

## 6. Further information

### What Sporanox oral solution contains:

- The active ingredient is itraconazole (10mg of itraconazole per ml).
- The other ingredients are hydroxypropyl- $\beta$ -cyclodextrin, sorbitol, propylene glycol, hydrochloric acid, cherry flavour, caramel flavour, sodium saccharin, sodium hydroxide and water.

### What Sporanox oral solution looks like and the contents of the pack:

Sporanox oral solution is a clear, yellow to slightly amber solution. It is available in bottles containing 150 ml together with a measuring cup.

### Marketing Authorisation Holder:

The UK Product Licence and Irish Product Authorisation for this medicine are held by:

Janssen-Cilag Ltd  
50-100 Holmers Farm Way  
High Wycombe  
Buckinghamshire  
HP12 4EG  
UK

### Manufacturer:

Sporanox oral solution is manufactured by:  
Janssen Pharmaceutica NV,  
Turnhoutseweg 30,  
B-2340 Beerse,  
Belgium.

**This medicinal product is authorised in the member states of the EEA under the following names:**

Austria: SPORANOX®  
Belgium: SPORANOX®  
Germany: SEMPERA®  
Spain: SPORANOX®  
Finland: SPORANOX®  
Ireland: SPORANOX®  
Italy: SPORANOX®  
Luxembourg: SPORANOX®  
Netherlands: TRISPORAL®  
Portugal: SPORANOX®  
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