PACKAGE LEAFLET: INFORMATION FOR THE USER
Sporanox I.V. 10 mg/ml concentrate and solvent for solution for infusion
(itraconazole)

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Sporanox I.V. is and what it is used for

Sporanox I.V. is one of a group of medicines called "antifungals". These medicines are used to treat infections caused by fungi including yeasts.

Sporanox I.V. is used to:
- Treat fungal infections of the internal organs.

2. What you need to know before you are given Sporanox I.V.

You should not be given Sporanox I.V. if:
- You are **allergic** (hypersensitive) to any of the ingredients in Sporanox I.V. (listed in section 6 Contents of the pack and other information)
- You are **pregnant**, think you might be pregnant or are trying to become pregnant, (see the section on Pregnancy)
- Your kidney function is seriously reduced
- You cannot have sodium chloride by injection.
- You are taking any of the following medicines:
    - terfenadine or mizolastine (antihistamines for allergies)
    - bepridil, ivabradine or ranolazine - used to treat angina (crushing chest pain)
    - nisoldipine, lercanidipine or eplerenone (used for high blood pressure)
    - cisapride (used for stomach upsets)
    - domperidone (for nausea and vomiting)
    - midazolam by mouth or triazolam (used to help you sleep or for anxiety)
    - lovastatin or simvastatin (used to lower cholesterol)
    - pimozide or sertindole (for conditions affecting thoughts, feelings and/or behaviour)
    -
    - dihydroergotamine or ergotamine (for migraine headaches)
    - ergometrine (ergonovine) or methylergometrine (methylergonovine) used after giving birth
    - disopyramide, dronedarone, quinidine or dofetilide (for irregular heart beat rhythms)
    - colchicine (for gout) when used in patients with kidney or liver problems
    - halofantrine (for malaria)

- irinotecan (for cancer)
- dabigatran (for blood thinning)
- quetiapine (for psychosis)
- aliskiren (for hypertension)
- fesoterodine (for irritated urinary bladder) when used in patients with certain kidney or liver problems
- sildenafil (for pulmonary arterial hypertension)
- solifenacin (for irritated urinary bladder) when used in patients with certain kidney or liver problems
- vardenafil (for erectile dysfunction) when used in men older than 75 years of age

Also, upon completing your course of Sporanox I.V., do not take any of the medicines listed above for 2 weeks.

Warnings and precautions
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.

You must tell your doctor before you are given Sporanox I.V. if you suffer from or have suffered in the past from any of the following:
- Any liver problems or jaundice (yellowing of the skin). If your doctor decides to give you Sporanox I.V. the dose may have to be changed. Your doctor may give you instructions on symptoms to watch out for and ask you to have your blood checked. In addition, there may be specific medication you may not be able to take.
- An allergic reaction to any other antifungal medicine.
- Heart problems, including heart failure (also called congestive heart failure or CHF), Sporanox could make it worse. If your doctor decides to give you Sporanox I.V. 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
- Are on a low salt diet.
- A kidney disorder, you may be monitored more closely or your dose of Sporanox may have to be changed. In addition, there may be specific medication you may not be able to take.

Other medicines and Sporanox I.V.
There are some medicines that **you should not take** whilst being given Sporanox. These are listed above under the heading "**You should not be given Sporanox I.V. if:"**

Tell your doctor if you are using the following as they may stop Sporanox I.V. from working properly:
- rifampicin, rifabutin or isoniazid (antibiotics used to treat tuberculosis)
- phenytoin, carbamazepine or phenobarbital (anti-epileptics)
- efavirenz or nevirapine (medicines used for HIV/AIDS)
- St John's Wort (a herbal medicine)

Do not use Sporanox I.V. within 2 weeks of taking these medicines.

Tell your doctor if you are using the following medicines as they are not recommended with Sporanox I.V. unless your doctor feels it is necessary:

- medicines for cancer (namely dasatinib, lapatinib, nilotinib, or trabectedin)
- rifabutin (for tuberculosis)
- carbamazepine (for epilepsy)
- colchicine (for gout)
- everolimus or temsirolimus (given after an organ transplant)
- fentanyl (for pain)
- rivaroxaban (for blood clots)
- salmeterol (for breathing problems)
- tamsulosin (for male urinary incontinence)
- vardenafil (for erectile dysfunction) when used in men 75 years of age and younger
- atorvastatin (for lowering levels of cholesterol)
- ciclesonide (for inflammation, asthma and allergies)
- ebastine (for allergies)
- eletriptan (for migraine headaches)
- tolterodine (for irritated urinary bladder)
- felodipine (for the heart or blood vessels)

Also, upon completing your course of Sporanox I.V., do not take any of the medicines listed above for 2 weeks.

Tell your doctor before taking any of the following medicines as the dose of Sporanox I.V. or other treatments may need to be altered:

- ciprofloxacin, clarithromycin or erythromycin (anitibiotics for infections)
- medicines that act on the heart or blood vessels (digoxin, nadolol, calcium channel blockers such as, dihydropyridines, verapamil)
- medicines that slow down blood clotting or thin the blood, such as the coumarins (e.g., warfarin) or cilostazol
- methylprednisolone, budesonide, fluticasone or dexamethasone, medicines given by mouth and injection for inflammation, asthma and allergies
- cyclosporine, tacrolimus or rapamycin (also known as sirolimus), which are usually given after an organ transplant
- medicines used in HIV-infected patients, such as maraviroc, ritonavir, ritonavir-boosted darunavir, ritonavir-boosted fosamprenavir, indinavir or saquinavir
- medicines for cancer (such as bortezomib, busulphan, docetaxel, erlotinib, gefitinib, imatinib, ixabepilone, trimetrexate or a group of medicines known as vinca alkaloids)
- alfentanil, buprenorphine or oxycodone (for pain)
- methadone for treatment of drug abuse (opioid-dependency)
- buspirone, alprazolam, brotizolam, perospirone or midazolam when given by injection into a vein (for anxiety or to help you sleep)
- reboxetine (for depression)
- repaglinide or saxagliptin (for diabetes)
- aripiprazole, haloperidol or risperidone (for psychosis)
- aprepitant (for nausea and vomiting)
- fesoterodine or solifenacin (for irritated urinary bladder)
- sildenafil or tadalafil (for erectile dysfunction)
- praziquantel (for fluke and tapeworms)
- meloxicam (for joint inflammation and pain)
- cinacalcet (for an over active parathyroid)
- tolvaptan (for low blood sodium levels)
- alitretinoin (oral) (for eczema)

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

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

Pregnancy
Do not take Sporanox I.V. 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 receiving your medicine. As Sporanox I.V. remains in the body for some time after you stop receiving it, you should continue to use some form of contraception until your next period after your treatment with Sporanox I.V. has finished.

If you do find that you are pregnant after receiving a course of Sporanox I.V., 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
You should stop breast-feeding before you are given 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.

3. How you will be given Sporanox I.V.

Your medicine will be given to you by your doctor or nurse. Sporanox I.V. concentrate is mixed with the sodium chloride solution in the bag and is then given by slow injection into a vein. This is called an intravenous (I.V.) infusion and will usually take about an hour. For the first two days, you will be given two infusions each day. From Day three onwards you will be given one infusion each day.

How much you will be given
The recommended dosage is as follows:

Adults:

Day 1 and Day 2 of the treatment:	Two 1-hour infusions of 200 mg Sporanox I.V. will be given each day as a 60 ml infusion.
From Day 3 onwards:	One 1-hour infusion of 200 mg Sporanox I.V. will be given each day as a 60 ml infusion.

Children:
Not recommended.

Elderly:
Not recommended.

If a dose is missed or you are given too much-Sporanox l.V
Since this medicine will be given to you by a doctor or nurse, it is unlikely that you will be given too much or that a dose will be missed. However, if you are worried, tell your doctor or nurse.

4. Possible side effects

Like all medicines, Sporanox I.V. 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 symptoms of hearing loss
- Severe upper stomach pain, often with nausea and vomiting due to inflammation of the pancreas (pancreatitis)

Other side effects include:
Very common side effects (occur in more than 1 in 10 patients)

- feeling sick (nausea)
- being sick (vomiting)
- diarrhoea
- cough
- rash
- general swelling

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

- headache, dizziness
- stomach ache, constipation
- increases in specific liver function tests (hepatic enzyme increased), inflammation of the liver (hepatitis), yellowing of the skin (jaundice)
- itching, hives
- fever or high temperature
- shortness of breath
- certain blood disorder which may increase the risk of infections (possible symptom of low levels of granulocytes)
- high blood sugar levels
- muscle cramps or irregular heart beat (possible symptoms of low blood levels of magnesium)
- confusion
- sleepiness
- tremors
- increase in heart rate
- high blood pressure
- low blood pressure
- fluid in the lungs
- indigestion

- hair loss
- excess sweating
- muscle pain
- kidney problems
- chest pain
- pain
- chills
- fatigue
- increase in blood urea levels
- abnormal urine findings
- injection site swelling

Uncommon side effects (occur in less than 1 in 100 patients) are:
- unpleasant taste
- muscle cramps or irregular heart beat (possible symptoms of high blood levels of potassium)
- certain blood disorder which may increase the risk of bleeding or bruising (possible symptoms of low levels of platelets)
- difficulty speaking
- decreased feeling or sensitivity, especially in the skin
- increase in blood creatine phosphokinase levels

The following side effects have been reported in patients taking Sporanox with unknown frequency:
- excess of triglycerides (fats) in the blood

The following side effects have been reported in patients taking other formulations of Sporanox:
- infection of the upper respiratory tract
- inflammation of the nose
- inflammation of the sinuses
- certain blood disorder which may increase the risk of infections (possible symptom of low levels of white blood cells)
- muscle cramps or irregular heart beat (possible symptoms of low blood levels of potassium)
- excess gas in the intestinal tract
- painful joints
- excessive urine production
- abnormal menstrual bleeding
- erectile dysfunction

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.
In the UK, you can also report side effects directly via the Yellow Card Scheme at:
www.mhra.gov.uk/yellowcard

In Ireland, you can also report side effects directly via:
HPRA Pharmacovigilance, Earlsfort
Terrace, IRL - Dublin 2, Tel: +353 1 6764971,
Fax: +353 1 6762517, Website: www.hpra.ie,
E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sporanox I.V.
Keep out of the reach and sight of children.

Sporanox I.V. will be kept in the hospital pharmacy.
The product should not be used after the expiry date printed on the inner and outer packaging. The expiry date refers to the last day of that month.
Do not store Sporanox I.V. concentrate above 25°C.
Store in the original container.
Do not store the bag containing Sodium Chloride above 25°C. Do not freeze.
Protect the mixed solution from direct sunlight. Once mixed, the product should be used immediately.

6. Contents of the pack and other information

What Sporanox I.V. contains:
- The active ingredient in Sporanox I.V.is itraconazole (10 mg of itraconazole per ml).
- The other ingredients are hydroxypropyl-β-cyclodextrin, propylene glycol, hydrochloric acid concentrated, sodium hydroxide and water for injections.

What 0.9% Sodium Chloride Injection contains:
- Sodium Chloride, water for injections.

What Sporanox I.V. looks like and the contents of the pack
It is a kit containing a clear, colourless concentrated solution for intravenous (I.V.) infusion, which means the solution needs to be diluted before use. Sporanox I.V. comes in a 25 millilitre (ml) ampoule, together with a bag containing a clear, colourless Sodium Chloride solution and an extension line. These two solutions will be mixed together to give a clear, colourless solution before they are given directly into your veins.

One ml of Sporanox I.V. concentrate contains 10 milligrams (mg) of itraconazole. When the Sporanox I.V. concentrate is added to the bag containing sodium chloride solution, each ml of the mixed solution contains 3.33 mg itraconazole.

The Sodium Chloride bag is a plastic polypropylene infusion bag, which contains 50 ml of Sodium Chloride solution. One ml of solution contains 9 mg sodium chloride. It is used to dilute the Sporanox I.V. concentrate making it easier to be given.

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

Manufacturer:
Sporanox I.V. 10mg/ml concentrate and solvent for solution for infusion are manufactured by:
Lusomedicamenta
Sociedade Técnica Farmacêutica S.A.
Estrada Consiglieri Pedroso, 69-B
Queluz
2730-055 Barcarena

Portugal

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

Germany: SEMPERA®
Spain: SPORANOX®
Ireland: SPORANOX®
Italy: SPORANOX®
Portugal: SPORANOX®
Greece: SPORANOX®
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