

Package leaflet: Information for the user

Sporanox® 100 mg capsules

itraconazole

Read all of this leaflet carefully before you start using 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 pharmacist
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Sporanox capsules are and what they are used for
2. What you need to know before you use Sporanox capsules
3. How to use Sporanox capsules
4. Possible side effects
5. How to store Sporanox capsules
6. Contents of the pack and other information

1. What Sporanox capsules are and what they are used for

The name of your medicine is Sporanox 100 mg capsules. It is called 'Sporanox capsules' in this leaflet.

Sporanox capsules contain a medicine called itraconazole. This belongs to a group of medicines called 'antifungals'.

Sporanox capsules are used in adults for infections caused by fungi or yeasts. They are used for:

- Infections of the mouth or vagina causing 'thrush'
- Skin infections
- Infections affecting other parts of the body

Patches of skin may take a few weeks to completely clear up after you have finished your treatment with Sporanox capsules. Finger and toe nails may take several months to completely clear up. This is because your skin or nail will only look normal after new skin or nail has grown, even though the medicine has killed the fungus that caused the infection.

2. What you need to know before you use Sporanox capsules

Do not use Sporanox capsules:

- **If you are allergic** (hypersensitive) to any of the ingredients in **Sporanox capsules** (listed in section 6)
- **If you are pregnant, think you might be pregnant or could become pregnant (see the section on Pregnancy)**
- If you have a serious heart condition called heart failure (also called congestive heart failure or CHF) unless your doctor has told you to (see 'Take special care with Sporanox capsules' below)

Do not use this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before using Sporanox capsules.

Tell your doctor if you are taking any medicines, before you use Sporanox capsules.

- Do not use Sporanox capsules if you are taking certain medicines, or within 2 weeks of stopping Sporanox capsules. The following list contains examples of medicines you must not take with Sporanox capsules, or within 2 weeks of stopping Sporanox capsules:

Medicines used 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 heartbeat rhythms)
- finerenone (for kidney problems in patients with type 2 diabetes)
- lomitapide, lovastatin or simvastatin (to lower cholesterol)
- sildenafil (for pulmonary arterial hypertension)

Medicines to treat stomach problems or constipation

- cisapride (for stomach upsets)
- domperidone (for nausea and vomiting)
- naloxegol (for constipation caused by taking opioid painkillers)

Medicines to treat headaches, sleep or mental health problems

- dihydroergotamine or ergotamine (ergot alkaloids used for migraine headaches)
- midazolam (taken by mouth) or triazolam (for sedation or to help you sleep)
- lurasidone, pimozone, quetiapine or sertindole (for schizophrenia, bipolar disorder or other mental health problems)

Medicines to treat urinary problems

- 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 erectile dysfunction)
- dapoxetine (for premature ejaculation)
- vardenafil (for erectile dysfunction) 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 methylethergometrine (methylethergonovine) ergot alkaloids used after giving birth
- eliglustat (for Gaucher's disease) when used in patients that cannot break down certain medicines in the body
- halofantrine (for malaria)
- irinotecan (for cancer)
- isavuconazole (for fungal infections)
- ombitasvir, paritaprevir, ritonavir with or without dasabuvir – (to treat hepatitis C)
- venetoclax (for chronic lymphocytic leukaemia) when you newly start venetoclax or take increasing doses at beginning of treatment
- voclosporin (to treat lupus-related kidney problems)

Remember – do not take any of the medicines above for 2 weeks after your last treatment with Sporanox capsules.

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

Warnings and precautions

Talk to your doctor or pharmacist before using Sporanox capsules if:

- You have ever had kidney problems. Your dose of Sporanox capsules may have to be changed
- You have ever had liver problems such as yellow skin (jaundice). Your dose of Sporanox capsules may need to be changed. If after taking this medicine you have a severe lack of appetite, feel sick (nausea), are sick (vomiting), feel unusually tired, get stomach pain, muscle weakness, yellowing of the skin or whites of the eyes, unusually dark urine, pale stools or hair loss, stop taking Sporanox capsules and tell your doctor straight away
- You have ever had a heart problem including heart failure (also called congestive heart failure or CHF). Sporanox capsules could make it worse. If after taking this medicine you get any of the following:

- shortness of breath
- unexpected weight gain
- swelling of your legs or tummy
- feel unusually tired
- wake up short of breath at night

stop taking Sporanox capsules and tell your doctor straight away. These may be signs of heart failure

- You have Acquired Immunodeficiency Syndrome (AIDS) or your immune system is not working as well as it should
- You have experienced an allergic reaction to another antifungal product in the past
- You have cystic fibrosis

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Sporanox capsules.

Children and adolescents

Sporanox should not be given to children or adolescents younger than 18 years of age.

The elderly

Sporanox capsules are not normally given to the elderly. However, your doctor may prescribe them in special cases.

Blood tests

If your Sporanox capsules course is for more than one month, your doctor may want to check your liver by testing your blood.

Other medicines and Sporanox capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription or herbal medicines.

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

Certain medicines are not recommended for use with Sporanox capsules.

Your doctor may decide that you **should not take some medicines at the same time as, or within 2 weeks of stopping** Sporanox capsules.

Examples of these medicines are:

Medicines to treat problems with the heart, blood or circulation

- apixaban, edoxaban, rivaroxaban or vorapaxar (for blood clots)
- atorvastatin (to lower cholesterol)
- 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 used for mental health problems)

Medicines to treat urinary problems

- tamsulosin (for male urinary incontinence)
- tolterodine (for irritated urinary bladder)

Medicines to treat cancer

- axitinib, bosutinib, cabazitaxel, cabozantinib, ceritinib, cobimetinib, crizotinib, dabrafenib, dasatinib, docetaxel, entrectinib, glasdegib, ibrutinib, lapatinib, nilotinib, olaparib, pazopanib, regorafenib, sunitinib, talazoparib, trabectedin, trastuzumab emtansine, venetoclax (when you are on a stable dose of venetoclax for chronic lymphocytic leukaemia, or at any time of treatment for acute myeloid leukaemia) or vinca alkaloids (e.g., vinflunine, vinorelbine)

Medicines to treat tuberculosis

- bedaquiline, isoniazid, rifabutin or rifampicin (for tuberculosis)

Medicines to treat human immunodeficiency virus (HIV) or hepatitis

- efavirenz or nevirapine (for HIV/AIDS)
- elbasvir/grazoprevir, tenofovir alafenamide fumarate (TAF), tenofovir disoproxil fumarate (TDF) (for HIV or hepatitis)

Medicines used after organ transplant

- everolimus, rapamycin (also known as sirolimus), temsirolimus

Medicines to treat benign prostatic enlargement

- alfuzosin, silodosin

Medicines to treat lung problems or allergies

- ciclesonide (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 erectile dysfunction)

Other medicines containing:

- colchicine (for gout)
- fentanyl (for pain)
- lumacaftor/ ivacaftor (for cystic fibrosis)

Remember - do not take any of the medicines above for 2 weeks after your last treatment with Sporanox capsules.

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

Care needs to be taken when using Sporanox capsules with certain other medicines.

You may be more likely to get side effects, or the dose of Sporanox capsules or the other medicine 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 diarrhoea

- aprepitant or netupitant (for nausea and vomiting during cancer treatment)
- loperamide (for diarrhoea)
- antacids such as aluminium, calcium, magnesium, or sodium bicarbonate; H₂-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, cariprazine, 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 urinary problems

- imidafenacin, fesoterodine, oxybutynin, solifenacin (for irritated urinary bladder)

Medicines to treat cancer

- bortezomib, brentuximab vedotin, busulfan, erlotinib, gefitinib, idelalisib, imatinib, nintedanib, panobinostat, pemigatinib, ponatinib, ruxolitinib, sonidegib or tretinoin (oral)

Medicines to treat infections

- ciprofloxacin, clarithromycin, or erythromycin (for bacterial infections)
- delamanid (for tuberculosis)
- artemether-lumefantrine or quinine (to treat malaria)
- praziquantel (for fluke and tapeworms)

Medicines to treat human immunodeficiency virus (HIV) or hepatitis

- cobicistat, ritonavir-boosted elvitegravir, maraviroc, ritonavir, boosted darunavir, ritonavir-boosted fosamprenavir, indinavir or ritonavir-boosted saquinavir (for HIV)
- glecaprevir/pibrentasvir (for hepatitis)

Medicines used after organ transplant

- cyclosporine 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, allergies or inflammatory conditions)
- budesonide or fluticasone (for asthma, allergies)

Medicines to treat erection and ejaculation problems

- sildenafil (for erectile dysfunction)

Medicines to treat pain

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

Other medicines containing:

- alitretinoin (given by mouth) (for eczema)
- cabergoline (for Parkinson's disease)
- cannabis based products including medicines (such as for nausea and vomiting or muscle spasms in patients with multiple sclerosis)
- cinacalcet (for an over active parathyroid)
- dienogest or ulipristal (contraceptives)
- eliglustat (for Gauchers disease) when used in patients that cannot break down certain medicines in the body
- ivacaftor; (for cystic fibrosis)
- methadone (to treat drug addiction)
- repaglinide or saxagliptin (for diabetes)

This is not a complete list, so tell your doctor if you are taking or planning to take any of these medicines, or any other medicines. They may need to alter the dose of Sporanox capsules or your other medicine.

Sporanox capsules with food and drink

Always take Sporanox capsules straight after a meal as this helps your body to use the medicine.

Pregnancy and breast-feeding

- Do not take Sporanox capsules if you are pregnant unless your doctor has told you to. You should use contraception to make sure that you do not become pregnant when taking this medicine
- The medicine in Sporanox capsules stays in your body for some time after you have stopped taking them. After your treatment has finished, you must use contraception up until your next period (menstrual bleed). Ask your doctor for advice on what type of contraception to use
- If you become pregnant after starting a course of Sporanox capsules, stop taking them and tell your doctor straight away
- Do not breast-feed if you are taking Sporanox capsules, as small amounts of the medicine could pass into your milk. Ask your doctor for advice

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

If you are of childbearing age and could become pregnant, talk to your doctor. You should use effective contraceptives to make sure that you do not become pregnant while you are taking your medicine.

Driving and using machines

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

Sporanox capsules contain sucrose (sugar)

If your doctor has told you that you are intolerant of some sugars, contact them before taking this medicine.

3. How to use Sporanox capsules

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Taking Sporanox capsules

- Always take Sporanox capsules straight after a meal as this helps your body to use the medicine
- Swallow the capsules whole with some liquid
- There must be enough acid in your stomach to make sure that your body can use the medicine. Medicines for indigestion, stomach ulcers or heartburn can affect the stomach producing acid. For this reason you should wait two hours after taking Sporanox capsules before taking any of these other medicines. If you do take medicines that stop the production of stomach acid, you should take Sporanox capsules with a drink of non-diet cola.

How much to take

Your doctor will tell you how many Sporanox capsules to take and for how long. The recommended dose in adults is:

Yeast infection of the vagina (thrush)

- Take 2 capsules in the morning and 2 capsules 12 hours later for 1 day only or 2 capsules a day for 3 days

Yeast infection of the mouth (oral thrush)

- Take 1 capsule each day for 14 days

Fungal infections of the skin

The dosage depends on your infection. Your doctor might tell you to take:

- 2 capsules each day for 7 days, or
- 1 capsule each day for 14 days, or
- 1 capsule each day for 28 days

Fungal infections in other parts of the body

Your doctor will tell you how many Sporanox capsules to take and for how long depending on your infection.

If you take more Sporanox capsules than you should

If you take more Sporanox capsules than you were told to, talk to your doctor or go to the nearest hospital casualty department straight away.

If you forget to take Sporanox capsules

- If you forget to take your capsules, take them as soon as you remember. However, if it is nearly time for the next capsules, skip the missed capsules
- Do not take a double dose to make up for a forgotten dose

If you stop taking Sporanox capsules

Keep taking Sporanox capsules for as long as your doctor has told you. Do not stop your treatment just because you feel better.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using Sporanox capsules and tell your doctor straight away if you notice or suspect any of the following. You may need urgent medical treatment.

- Sudden signs of allergy such as rash, hives (also known as nettle rash or urticaria), severe irritation of your skin, swelling of the face, lips, tongue or other parts of the body. These may be signs of a severe allergic reaction. This only happens in a small number of people
- Severe skin disorders with peeling and/or rashes with small pustules (with a fever) or blistering of the skin, mouth, eyes and genitals, with fever, chills, aching muscles and generally feeling unwell. (This occurs rarely)
- A tingling sensation, numbness or weakness in your limbs (This occurs rarely)
- Severe lack of appetite, feeling sick (nausea), being sick (vomiting), unusual tiredness, stomach pain, muscle weakness, yellowing of your skin or whites of your eyes (jaundice), unusually dark urine, pale stools or hair loss. These may be signs of a liver problem. This only happens in a small number of people
- Shortness of breath, unexpected weight gain, swelling of your legs or abdomen, feeling unusually tired or waking up short of breath at night. These may be signs of heart failure. Shortness of breath can also be a sign of fluid on the lungs. (This occurs rarely)

Tell your doctor or pharmacist if you notice any of the following side effects:

Common (affects less than 1 in 10 people)

- Stomach ache, feeling sick (nausea)
- Headache

Uncommon (affects less than 1 in 100 people)

- Problems with periods
- Sinusitis, runny nose, coughs and colds
- Constipation, diarrhoea, wind, being sick (vomiting), indigestion

Rare (affects less than 1 in 1000 people)

- Increases in liver function tests (shown by blood tests)
- Unexpected passing of urine or need to urinate (pass water) more often
- Problems with sight including blurred vision and double vision
- Change in taste
- Certain blood disorders which may increase the risk of infections
- Ringing in your ears
- Hearing loss (may be permanent)
- Severe upper stomach pain, often with nausea and vomiting (inflammation of the pancreas)
- Swelling due to fluid under the skin
- Unusual hair loss or thinning (alopecia)
- High levels of triglycerides in the blood (shown by blood tests)
- Red, itchy, flaking or peeling skin
- Sensitivity of the skin to light
- Erection difficulties
- Tremor

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. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sporanox capsules

- Keep this medicine out of the sight and reach of children.
- Store the capsules in the carton to protect from light.
- Do not store above 30 °C.
- Do not use this medicine after the expiry date which is stated on the carton and label after 'EXP' or on the blister after 'ΑΗΕΗ' or 'EXP'. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Contents of the pack and other information

Sporanox capsules contain

The active substance is itraconazole. Each capsule contains 100 mg of itraconazole.

The other ingredients are sugar spheres, hypromellose and macrogol. The capsule is made of gelatin and the colours titanium dioxide (E171), indigotin disulphonate sodium (E132) and erythrosine (E127). See section 2 'Sporanox capsules contain sucrose (sugar)' for further information.

What Sporanox capsules look like and contents of the pack

Sporanox capsules are hard capsules coloured pink and blue. They are supplied in blister packs of 14, 15 or 28 capsules.

Product procured from within the EU, repackaged and distributed by the Parallel Product

Authorisation holder:

PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Manufacturer

Janssen-Cilag SpA, Via C Janssen, 04100 Borgo San Michele, Latina, Italy or Janssen-Cilag SpA, Via C. Janssen, 04010 Borgo San Michele, Latina, Italy.

Parallel Product Authorisation Number: PPA0465/400/001

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