

PACKAGE LEAFLET: INFORMATION FOR THE USER

Sporanox[®]-Pulse

Itraconazole

Sporanox is a registered trademark

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. Do not pass it on to others. It may harm them, even if their symptoms 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.

What is in this leaflet

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

1. What Sporanox-Pulse is and what it is used for

Sporanox-Pulse contains a medicine called itraconazole. This belongs to a group of medicines called 'antifungals'.

Sporanox-Pulse is used for infections caused by fungi or yeasts. It is used for:

- Nail infections
- Skin infections of the hands or feet

Patches of skin may take a few weeks to completely clear up after you have finished your treatment with Sporanox-Pulse. This is because your skin will only look normal after new skin has grown, even though the medicine has killed the fungus that caused the infection.

2. What you need to know before you use Sporanox-Pulse

Do not use Sporanox-Pulse if:

- You are allergic to anything in Sporanox-Pulse (listed in section 6 below)
- You are pregnant or could become pregnant (see 'Pregnancy and breast-feeding' 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-Pulse.

Warnings and precautions

Check with your doctor or pharmacist before using this medicine if:

- You have ever had kidney problems. Your dose of Sporanox-Pulse may have to be changed

- You have ever had liver problems such as yellow skin (jaundice). Your dose of Sporanox-Pulse may have 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-Pulse and tell your doctor straight away
- You have ever had a heart problem including heart failure (also called congestive heart failure or CHF). Sporanox-Pulse 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-Pulse 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 had an allergic reaction to another antifungal product in the past

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

Children and the elderly

Sporanox-Pulse is not normally given to children under the age of 12 or the elderly. However, your doctor may prescribe it in special cases.

Blood tests

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

Other medicines and Sporanox-Pulse

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription or herbal medicines.

In particular, do not take the following list of medicines with Sporanox-Pulse and tell your doctor if you are taking any of these:

- Medicines for hay fever or allergy called terfenadine, astemizole or mizolastine
- Medicines to lower cholesterol called lovastatin or simvastatin
- Medicines for an irregular heart beat called quinidine, dronedarone, dofetilide or disopyramide
- Medicines used to treat angina (crushing chest pain) and high blood pressure called bepridil, felodipine, lercanidipine, ivabradine, ranolazine and nisoldipine
- Medicines for migraine headaches called dihydroergotamine and ergotamine
- Medicines for the treatment of drug abuse called levacetylmethadol and methadone
- Cisapride - for digestive problems

- Colchicine (in patients with kidney and liver problems as well) – for gout
- Eplerenone – a diuretic
- Ergometrine (ergonovine) and methylergometrine (methylergonovine) - used after giving birth
- Halofantrine - for malaria
- Irinotecan – for cancer
- Midazolam (by mouth) or triazolam - for anxiety or to help you sleep
- Pimozide, lurasidone and sertindole - for conditions affecting thoughts, feelings and behaviour

Do not start taking Sporanox-Pulse and tell your doctor if you are taking any of the above. Also, upon completing your course of Sporanox-Pulse, do not take any of the medicines listed above for 2 weeks.

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

- Medicines for the treatment of cancer called dasatinib, nilotinib and trabectedin
- Aliskiren – for high blood pressure
- Colchicine – for gout
- Everolimus – usually given after an organ transplant
- Fentanyl – a strong painkiller
- Rivaroxaban – a medicine to thin blood
- Salmeterol – for asthma and other breathing problems
- Tamsulosin - for urinary incontinence in men
- Vardenafil – for erection problems

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

Do not take any of following medicines 2 weeks before and while you are taking Sporanox-Pulse unless your doctor tells you otherwise:

- Medicines for tuberculosis called rifampicin, rifabutin or isoniazid
- Medicines for epilepsy called carbamazepine, phenytoin or phenobarbital
- Medicines to treat viral infections called efavirenz or nevirapine

Tell your doctor before taking, or if you are already taking, any of the following medicines. They may stop Sporanox-Pulse from working properly. Your doctor may need to alter the dose of Sporanox-Pulse or your other medicine:

- Strong painkillers called alfentanil, buprenorphine (by injection or under your tongue) and oxycodone
- Medicines for indigestion, stomach ulcers or heartburn can affect the stomach producing acid. There must be enough acid in your stomach to make sure that your body can use the medicine. For this reason you should wait at least an hour after taking one of these other medicines before taking Sporanox-Pulse or wait for two hours after taking Sporanox-Pulse before taking any of these other medicines. If you take medicines that stop the production of stomach acid, you should take Sporanox-Pulse with a drink of cola (not diet cola)
- Medicines used for anxiety or to help you sleep (tranquillisers), such as buspirone, alprazolam or brotizolam

- Medicines used in the treatment of cancer such as bortezomib, busulphan, docetaxel, erlotinib, ixabepilone, lapatinib, trimetrexate and a group of medicines known as 'vinca alkaloids'
- Medicines for conditions affecting thoughts, feelings and behaviour called aripiprazole, haloperidol, perospirone, quetiapine, ramelteon and risperidone
- Medicines to thin the blood (anticoagulants) such as warfarin, cilostazol and dabigatran
- Medicines for HIV infection such as ritonavir, darunavir, indinavir fosamprenavir and saquinavir. (They are called 'antiviral protease inhibitors'.) Also maraviroc
- Medicines for bacterial infections called ciprofloxacin, clarithromycin or erythromycin
- Medicines that act on the heart and blood vessels called nadolol, digoxin, cilostazol or 'calcium channel-blockers' such as dihydropyridines or verapamil
- Medicines for inflammation, asthma or allergies (given by mouth or injection) called methylprednisolone or fluticasone, budesonide or dexamethasone
- Medicines that are usually given after an organ transplant called ciclosporin, tacrolimus, rapamycin (also known as sirolimus) or temsirolimus.
- Medicines to treat an overactive bladder – fesoterodine, imidafenacin, solifenacin or tolterodine
- Alitretinoin (by mouth) – for eczema
- Aprepitant and domperidone – to stop you feeling and being sick
- Atorvastatin – to lower cholesterol
- Cinacalcet – for an over active parathyroid gland
- Ebastine - for allergy
- Eletriptan - for migraine headaches
- Mozavaptan or tolvaptan– for low sodium blood levels
- Praziquantel – for treatment of worms
- Reboxetine - for depression
- Repaglinide or saxagliptin - for diabetes
- Midazolam - to help you relax or sleep when given into a vein
- Sildenafil and tadalafil – for erection problems

Tell your doctor before taking, or if you are already taking any of the above. They may need to alter the dose of Sporanox-Pulse or your other medicine.

Taking Sporanox-Pulse with food and drink

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

Pregnancy and breast-feeding

- Do not take Sporanox-Pulse if you are pregnant. You should use contraception to make sure that you do not become pregnant when taking this medicine
- The medicine in Sporanox-Pulse stays in your body for some time after you have stopped taking it. 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-Pulse, stop taking them and tell your doctor straight away

- Do not breast-feed if you are taking Sporanox-Pulse, 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.

Driving and using machines

Sporanox-Pulse 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-Pulse

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

3. How to use Sporanox-Pulse

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

Taking Sporanox-Pulse

- Always take Sporanox-Pulse 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-Pulse before taking any of these other medicines. If you do take medicines that stop the production of stomach acid, you should take Sporanox-Pulse with a drink of cola

How much to take

Your doctor will tell you how many Sporanox-Pulse capsules to take and for how long. They may recommend the following treatment courses.

Skin infections on hands or feet

- Take 2 capsules of Sporanox-Pulse twice a day for one week

Fingernail infections only (see table below)

- Week 1: take 2 capsules of Sporanox-Pulse twice a day for this week
- Weeks 2, 3 and 4: do not take Sporanox-Pulse for these next 3 weeks
- Week 5: take 2 capsules of Sporanox-Pulse twice a day for this week.
This completes the treatment course

Toenail infections with or without fingernail infections (see table below)

- Week 1: take 2 capsules of Sporanox-Pulse twice a day for this week
- Weeks 2, 3 and 4: do not take Sporanox-Pulse for these next 3 weeks
- Week 5: take 2 capsules of Sporanox-Pulse twice a day for this week
- Weeks 6, 7 and 8: do not take Sporanox-Pulse for these next 3 weeks
- Week 9: take 2 capsules of Sporanox-Pulse twice a day for this week.
This completes the treatment course

	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10
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Finger nails only	Take 2 capsules twice a day	No Sporanox-Pulse	Take 2 capsules twice a day	Stop		
Toe nails with or without finger nail infections	Take 2 capsules twice a day	No Sporanox-Pulse	Take 2 capsules twice a day	No Sporanox-Pulse	Take 2 capsules twice a day	Stop

If you take too much of your medicine

If you take more Sporanox-Pulse 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-Pulse

- 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

When to stop using Sporanox-Pulse

Keep taking Sporanox-Pulse for as long as your doctor has told you. Do not stop your treatment just because your skin or nails have improved.

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

4. Possible side effects

Like all medicines, Sporanox-Pulse can cause side effects, although not everybody gets them.

Stop using Sporanox-Pulse 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

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Sporanox-Pulse

Keep out of the reach and sight of children.

- Store the capsules in their carton
- Keep the carton in a dry place out of strong sunlight
- Do not store above 30°C
- Do not use Sporanox-Pulse after the expiry date which is stated on the label. The expiry date refers to the last day of that month

Medicines should not be disposed of 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

The active substance in Sporanox-Pulse 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).

What Sporanox-Pulse looks like and contents of the pack

Sporanox-Pulse capsules are pink and blue. They are supplied in blister packs of 28 capsules.

The product licence is held by:

JANSSEN-CILAG LTD, 50-100 Holmers Farm Way, High Wycombe,
Buckinghamshire HP12 4EG, UK

Sporanox-Pulse is made by:

Janssen Pharmaceutica NV, Turnhoutseweg 30, B-2340 Beerse, Belgium

OR

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

**For information in large print, tape, CD or Braille, telephone
0800 7318450.**

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