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 (hypersensitive) to any of the ingredients in Sporanox-Pulse capsules (listed in section 6 Contents of the pack and other information)
- You are pregnant, think you might be pregnant or could become pregnant (see ‘Pregnancy and breast-feeding’ below)

Tell your doctor if you are taking any medicines, before you use Sporanox-Pulse capsules.
• Do not use Sporanox-Pulse capsules if you are taking any of the following medicines, or within 2 weeks of stopping Sporanox-Pulse:

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 heart beat rhythms)
  - 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, pimozide, 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 methylergometrine (methylergonovine) 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)
Remember – do not take any of the medicines above for 2 weeks after your last treatment with Sporanox-Pulse capsules.

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 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-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:
  o shortness of breath
  o unexpected weight gain
  o swelling of your legs or tummy
  o feel unusually tired
  o 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 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-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, 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-Pulse. These are listed above under the heading “Do not use Sporanox-Pulse capsules if you are:”

Certain medicines are not recommended for use with Sporanox-Pulse capsules. Your doctor may decide that you should not take some medicines at the same time as, or within 2 weeks of stopping Sporanox-Pulse capsules.

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)
- 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, ibrutinib, lapatinib, nilotinib, olaparib, pazopanib, regorafenib, sunitinib, trabectedin, trastuzumab emtansine, or vinca alkaloids (eg, 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, simeprevir, 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)
Remember - do not take any of the medicines above for 2 weeks after your last treatment with Sporanox-Pulse 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-Pulse capsules with certain other medicines. You may be more likely to get side effects, or the dose of Sporanox-Pulse 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, ponatinib, ruxolitinib or sonidegib

**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, boosted elvitegravir, maraviroc, ritonavir, ritonavir-boosted darunavir, ritonavir-boosted fosamprenavir, indinavir or 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)
- levacetylmethadol and 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-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. 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.

- 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.

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### 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 non-diet 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

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<td><strong>Finger nails</strong> only</td>
<td>Take 2 capsules twice a day</td>
<td>No Sporanox-Pulse</td>
<td>Take 2 capsules twice a day</td>
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<tr>
<td><strong>Toe nails</strong> with or without finger nail infections</td>
<td>Take 2 capsules twice a day</td>
<td>No Sporanox-Pulse</td>
<td>Take 2 capsules twice a day</td>
<td>No Sporanox-Pulse</td>
<td>Take 2 capsules twice a day</td>
<td>Stop</td>
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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
- 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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

### 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
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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