

Patient Information

SPORANOX[®]

(itraconazole) Capsules

This summary contains important information about SPORANOX[®] (SPOR-ah-nox). This information is for patients who have been prescribed SPORANOX[®] to treat fungal nail infections. **If your doctor prescribed SPORANOX[®] for medical problems other than fungal nail infections, ask your doctor if there is any information in this summary that does not apply to you.** Read this information carefully each time you start to use SPORANOX[®]. This information does not take the place of discussion between you and your doctor. Only your doctor can decide if SPORANOX[®] is the right treatment for you. If you do not understand some of this information or have any questions, talk with your doctor or pharmacist.

What Is The Most Important Information I Should Know About SPORANOX[®] ?

SPORANOX[®] is used to treat fungal nail infections. However, SPORANOX[®] is not for everyone.

Do not take SPORANOX[®] for fungal nail infections if you have had heart failure, including congestive heart failure. You should not take SPORANOX[®] if you are taking certain medicines that could lead to serious or life-threatening medical problems. (See “Who Should Not Take SPORANOX[®]?” below).

If you have had heart, lung, liver, kidney or other serious health problems, ask your doctor if it is safe for you to take SPORANOX[®].

What Happens If I Have A Fungal Nail Infection?

Anyone can have a fungal nail infection, but it is usually found in adults. When a fungus infects the tip or sides of a nail, the infected part of the nail may turn yellow or brown. If not treated, the fungus may spread under the nail towards the cuticle. If the fungus spreads, more of the nail may change color, may become thick or brittle, and the tip of the nail may become raised. In some patients, this can cause pain and discomfort.

What Is SPORANOX®?

SPORANOX® is a prescription medicine used to treat fungal infections of the toenails and fingernails. It is also used to treat some types of fungal infections in other areas of your body. We do not know if SPORANOX® works in children with fungal nail infections or if it is safe for children to take.

SPORANOX® comes in the form of capsules and liquid (oral solution). The capsule and liquid forms work differently, so you should not use one in place of the other. This Patient Information discusses only the capsule form of SPORANOX®. You will get these capsules in a medicine bottle or a SPORANOX *PulsePak*®. The *PulsePak*® contains 28 capsules for treatment of your fungal nail infection.

SPORANOX® goes into your bloodstream and travels to the source of the infection underneath the nail so that it can fight the infection there. Improved nails may not be obvious for several months after the treatment period is finished because it usually takes about 6 months to grow a new fingernail and 12 months to grow a new toenail.

Who Should Not Take SPORANOX®?

SPORANOX® is not for everyone. Your doctor will decide if SPORANOX® is the right treatment for you. **Some patients should not take SPORANOX® because they may have certain health problems or may be taking certain medicines that could lead to serious or life-threatening medical problems.**

Tell your doctor and pharmacist the name of all the prescription and non-prescription medicines you are taking, including dietary supplements and herbal remedies. Also tell your doctor about any other medical conditions you have had, especially heart, lung, liver or kidney conditions.

Never take SPORANOX[®] if you:

- have had heart failure, including congestive heart failure.
- are taking any of the medicines listed below. Dangerous or even life-threatening abnormal heartbeats could result:
 - quinidine (such as Cardioquin[®], Quinaglute[®], Quinidex[®])
 - dofetilide (such as Tikosyn[™])
 - cisapride (such as Propulsid[®])
 - pimozide (such as Orap[®])
- are taking any of the following medicines:
 - lovastatin (such as Mevacor[®], Advicor[™], Altocor[™])
 - simvastatin (such as Zocor[®])
 - triazolam (such as Halcion[®])
 - midazolam (such as Versed[®])
- have ever had an allergic reaction to itraconazole or any of the other ingredients in SPORANOX[®] Capsules. Ask your doctor or pharmacist for a list of these ingredients.

What Should I Know About SPORANOX[®] and Pregnancy or Breast Feeding?

Never take SPORANOX[®] if you have a fungal nail infection and are pregnant or planning to become pregnant within 2 months after you have finished your treatment.

If you are able to become pregnant, you should use effective birth control during SPORANOX[®] treatment and for 2 months after finishing treatment. Ask your doctor about effective types of birth control.

If you are breast-feeding, talk with your doctor about whether you should take Sporanox[®].

How Should I Take SPORANOX[®]?

Always take SPORANOX[®] Capsules during or right after a full meal.

Your doctor will decide the right dose for you. Depending on your infection, you will take SPORANOX[®] once a day for 12 weeks, or twice a day for 1 week in a “pulse” dosing schedule. You will receive either a bottle of capsules or a *PulsePak*[®]. Do not skip any doses. Be sure to finish all your SPORANOX[®] as prescribed by your doctor.

If you have ever had liver problems, your doctor should do a blood test to check your condition. If you haven't had liver problems, your doctor may recommend blood tests to check the condition of your liver because patients taking SPORANOX[®] can develop liver problems.

If you forget to take or miss doses of SPORANOX[®], ask your doctor what you should do with the missed doses.

The SPORANOX *PulsePak*[®]

If you use the *PulsePak*[®], you will take SPORANOX[®] for 1 week and then take no SPORANOX[®] for the next 3 weeks before repeating the 1-week treatment. This is called “pulse dosing.” The SPORANOX *PulsePak*[®] contains enough medicine for one “pulse” (1 week of treatment).

The SPORANOX *PulsePak*[®] comes with special instructions. It contains 7 pouches—one for each day of treatment. Inside each pouch is a card containing 4 capsules. Looking at the back of the card, fold it back along the dashed line and peel away the backing so that you can remove 2 capsules.

Week 1	//	//	//	//	//	//	//	//	//	//	//	//	//	//
Week 2	<p>For the next 3 weeks, do not take any SPORANOX[®] capsules.</p> <p>Remember to get a refill before the end of Week 4</p> <p>when your doctor prescribes another <i>PulsePak</i>[®].</p>													
Week 3														
Week 4														

What Are the Possible Side Effects of SPORANOX[®]?

The most common side effects that cause people to stop treatment either for a short time or completely include: skin rash, high triglyceride test results, high liver test results, and digestive system problems (such as nausea, bloating, and diarrhea).

Stop SPORANOX[®] and call your doctor right away if you develop shortness of breath; have unusual swelling of your feet, ankles or legs; suddenly gain weight; are unusually tired; cough up white or pink phlegm; or have unusual fast heartbeats. In rare cases, patients taking SPORANOX[®] could develop serious heart problems, and these could be warning signs of heart failure.

Stop SPORANOX[®] and call your doctor right away if you become unusually tired; lose your appetite; or develop nausea or vomiting, a yellow color to your skin or eyes, or dark colored urine or pale stools (bowel movements). In rare cases, patients taking SPORANOX[®] could develop serious liver problems and these could be warning signs.

Call your doctor right away if you develop tingling or numbness in your extremities (hands or feet).

These are not all the side effects of SPORANOX[®]. Your doctor or pharmacist can give you a more complete list.

What Should I Do If I Take An Overdose of SPORANOX[®]?

If you think you took too much SPORANOX[®], call your doctor or local poison control center, or go to the nearest hospital emergency room right away.

How Should I Store SPORANOX[®]?

Keep all medicines, including SPORANOX[®], out of the reach of children.

Store SPORANOX[®] Capsules and the *PulsePak*[®] at room temperature in a dry place away from light.

General Advice About SPORANOX[®]

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use SPORANOX[®] for a condition for which it was not prescribed. Do not give SPORANOX[®] to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about SPORANOX[®]. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about SPORANOX[®] that is written for health professionals.

You can also call 1-800-JANSSEN or visit the SPORANOX[®] Internet site at www.sporanox.com and the Janssen Internet site at www.us.janssen.com.

This patient information has been approved by the U.S. Food and Drug Administration.

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