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**Patient Information**

**March 26, 2002**

**SPORANOX<sup>®</sup>**

**(itraconazole) Capsules**

*strikeout=deleted*

*double underline=added*

**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.

17 **What Is The Most Important Information I Should Know About SPORANOX?**

18

19 SPORANOX is used to treat fungal nail infections. However, SPORANOX is not for  
20 everyone. **Do not take SPORANOX for fungal nail infections if you have had heart**  
21 **failure, including congestive heart failure. You should not take SPORANOX if you are**  
22 **taking certain medicines that could lead to serious or life-threatening medical problems.**  
23 (See “Who Should Not Take SPORANOX?” below).

24

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

27

28 **What Happens If I Have A Fungal Nail Infection?**

29

30 Anyone can have a fungal nail infection, but it is usually found in adults. When a fungus infects  
31 the tip or sides of a nail, the infected part of the nail may turn yellow or brown. If not treated, the  
32 fungus may spread under the nail towards the cuticle. If the fungus spreads, more of the nail may

33 change color, may become thick or brittle, and the tip of the nail may become raised. In some  
34 patients, this can cause pain and discomfort.

35  
36 **What Is SPORANOX?**

37  
38 SPORANOX is a prescription medicine used to treat fungal infections of the toenails and  
39 fingernails. It is also used to treat some types of fungal infections in other areas of your body.  
40 We do not know if SPORANOX works in children with fungal nail infections or if it is safe for  
41 children to take.

42  
43 SPORANOX comes in the form of capsules and liquid (oral solution). The capsule and liquid  
44 forms work differently, so you should not use one in place of the other. This Patient Information  
45 discusses only the capsule form of SPORANOX. You will get these capsules in a medicine  
46 bottle or a SPORANOX *PulsePak*®. The *PulsePak* contains 28 capsules for treatment of your  
47 fungal nail infection.

48  
49 SPORANOX goes into your bloodstream and travels to the source of the infection underneath

50 the nail so that it can fight the infection there. Improved nails may not be obvious for several  
51 months after the treatment period is finished because it usually takes about 6 months to grow a  
52 new fingernail and 12 months to grow a new toenail.

53

#### 54 **Who Should Not Take SPORANOX?**

55

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

60

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

64

65 **Never** take SPORANOX if you:

66

67 • have had heart failure, including congestive heart failure.

68

69 • are taking any of the medicines listed below. Dangerous or even life-threatening

70 abnormal heartbeats could result:

71 • quinidine (such as Cardioquin<sup>®</sup>, Quinaglute<sup>®</sup>, Quinidex<sup>®</sup>)

72 • dofetilide (such as Tikosyn<sup>™</sup>)

73 • cisapride (such as Propulsid<sup>®</sup>)

74 • pimozone (such as Orap<sup>®</sup>)

75

76 • are taking any of the following medicines:

77 • lovastatin (such as Mevacor<sup>®</sup>)

78 • simvastatin (such as Zocor<sup>®</sup>)

79 • triazolam (such as Halcion<sup>®</sup>)

80 • midazolam (such as Versed<sup>®</sup>)

81

- 82 • have ever had an allergic reaction to itraconazole or any of the other ingredients in  
83 SPORANOX Capsules. Ask your doctor or pharmacist for a list of these ingredients.

84

85 **What Should I Know About SPORANOX and Pregnancy or Breast Feeding?**

86

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

89

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

93

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

95

96 **How Should I Take SPORANOX?**

97

98 Always take SPORANOX Capsules during or right after a full meal.

99

100 Your doctor will decide the right dose for you. Depending on your infection, you will take  
101 SPORANOX once a day for 12 weeks, or twice a day for 1 week in a “pulse” dosing schedule.

102 You will receive either a bottle of capsules or a *PulsePak*. Do not skip any doses. Be sure to  
103 finish all your SPORANOX as prescribed by your doctor.

104 If you have ever had liver problems, your doctor should do a blood test to check your  
105 condition. If you haven’t had liver problems, your doctor may recommend blood tests to  
106 check the condition of your liver because patients taking ~~itraconazole~~ SPORANOX can  
107  
108 develop liver problems.  
109  
110

111  
112 If you forget to take or miss doses of SPORANOX, ask your doctor what you should do with  
113 the missed doses.

114

115 **The SPORANOX *PulsePak***

116

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

120

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

125

126 • Take 2 capsules in the morning and 2 capsules in the evening. This means you will take  
127 4 capsules a day for 7 days. At the end of 7 days, you will have taken all of the capsules  
128 in the *PulsePak* box.

129

130 • After you finish the *PulsePak*, do not take any SPORANOX for the next 3 weeks. Even  
131 though you are not taking any capsules during this time, SPORANOX keeps working  
132 inside your nails to help fight the fungal infection.



133

- 134 • You will need more than one “pulse” to treat your fungal nail infection. When your  
135 doctor prescribes another pulse treatment, be sure to get your refill before the end of  
136 week 4.

137

138

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141

<b>SPORANOX Pulse Dosing</b>							
<b>Take 2 SPORANOX capsules twice a day for 1 week</b>							
	<b>Day1</b>	<b>Day 2</b>	<b>Day 3</b>	<b>Day 4</b>	<b>Day 5</b>	<b>Day 6</b>	<b>Day 7</b>

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

142

143 **What Are the Possible Side Effects of SPORANOX?**

144

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

148

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

154

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

159

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

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

164

#### 165 **What Should I Do If I Take An Overdose of SPORANOX?**

166

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

169

#### 170 **How Should I Store SPORANOX?**

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172 Keep all medicines, including SPORANOX, out of the reach of children.

173

174 Store SPORANOX Capsules and the *PulsePak* at room temperature in a dry place away from  
175 light.

176

177 **General Advice About SPORANOX**

178

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

183

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

187

188 You can also call 1-800-JANSSEN or visit the SPORANOX Internet site at  
189 **www.sporanox.com** and the Janssen Internet site at **www.us.janssen.com**.

190

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

192

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195 (Roche Pharmaceuticals), Cardioquin<sup>®</sup> (The Purdue Frederick Company), Quinaglute<sup>®</sup> (Berlex

196 Laboratories), Quinidex<sup>®</sup> (A.H. Robins), Tikosyn<sup>™</sup> (Pfizer, Inc.), Propulsid<sup>®</sup> (Janssen

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