

1 **F-31157528T**

PATIENT INFORMATION

2
3 **NOXAFIL[®]**
4 (posaconazole) ORAL SUSPENSION

5
6 Read the Patient Information that comes with NOXAFIL[®] Oral Suspension before
7 you start taking it and each time you get a refill. There may be new information.
8 This information does not replace talking with your doctor about your condition or
9 treatment. Only your doctor can prescribe NOXAFIL and determine if it is right for
10 you.

11
12 **What is NOXAFIL[®]?**

- 13
- 14 • NOXAFIL is a prescription medicine that is used to prevent invasive fungal
15 infections (infections that can spread throughout the body) caused by *Aspergillus*
16 or *Candida* in patients with weak immune systems because of medicines or
17 diseases [such as stem cell transplantation with graft-vs.-host disease or
18 chemotherapy for hematologic malignancy (blood cancers)].
 - 19 • NOXAFIL is also used to treat fungal infections in the mouth or throat area
20 (known as “thrush”) caused by fungi called *Candida*. NOXAFIL can be used as
21 initial treatment or as a treatment after itraconazole and/or fluconazole have
22 failed.

23
24 NOXAFIL is for adults and children over 13 years of age.

25
26 **What should I tell my doctor before taking NOXAFIL[®]?**

27 Tell your doctor about all your health conditions, including if you:

- 28 • are taking certain drugs that suppress your immune system like **cyclosporine**
29 (**Neoral[®]**), or **tacrolimus (Prograf[®])**. Serious and rare fatal toxicity from
30 cyclosporine has occurred when taken in combination with posaconazole and,
31 therefore, reduction of the dose of drugs like **cyclosporine**, or **tacrolimus** and
32 frequent monitoring of drug levels of these medicines is necessary when taking
33 them in combination with NOXAFIL.
- 34 • are taking certain drugs for HIV infection, such as **ritonavir**, **atazanavir**, or
35 **efavirenz**. Frequent monitoring of drug levels of ritonavir and/or atazanavir is
36 necessary when taking them in combination with NOXAFIL. Efavirenz can cause
37 a decrease in NOXAFIL levels in the body, and, therefore, it is recommended
38 that efavirenz should not be administered with NOXAFIL.
- 39 • are taking **midazolam**, a hypnotic and sedative medication. NOXAFIL in
40 combination with midazolam increases the midazolam plasma concentrations,
41 which could increase and prolong sleepiness.
- 42 • have ever had an allergic reaction to other antifungal medicines such as
43 ketoconazole, fluconazole, itraconazole, or voriconazole.
- 44 • are taking any other medicines, including prescription and nonprescription
45 medicines, vitamins, and herbal supplements.

- 46 • have, or have had, liver problems. Your doctor may do blood tests to make sure
47 you should take NOXAFIL.
48 • have, or have had, an abnormal heart rate or rhythm.
49 • are, or think you are, pregnant. Do not use NOXAFIL during pregnancy unless
50 specifically advised by your doctor. You should use effective birth control while
51 you are taking NOXAFIL if you are a woman who could become pregnant.
52

53 Contact your doctor immediately if you become pregnant while being treated with
54 NOXAFIL.

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56 Do not breastfeed while being treated with NOXAFIL, unless specifically advised by
57 your doctor.
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59

60 **Who should not take NOXAFIL®?**

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62 - Do NOT take NOXAFIL if you are taking any of the medicines listed below.
63 If any of these medicines are taken together with NOXAFIL, serious or life-
64 threatening side effects from these medicines, or a decrease in the effect of
65 NOXAFIL can occur. Tell your doctor right away if you are taking any of
66 these medicines:

- 67 • sirolimus
68 • ergot alkaloids (ergotamine, dihydroergotamine, methylsergide,
69 methylergonovine, ergonovine, or bromocriptine)
70 • pimozide
71 • quinidine
72 • simvastatin
73 • rifabutin
74 • phenytoin
75 • cimetidine

76

77 - If you have questions or are uncertain about your medicines, talk with your
78 doctor or pharmacist.

79 - Do not take NOXAFIL if you are allergic to anything in it. There is a list of what
80 is in NOXAFIL at the end of this leaflet.

81

82 **Can I take other medicines with NOXAFIL®?**

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84 NOXAFIL and many medicines can interact with each other, and some must not be
85 taken together (see “**Who should not take NOXAFIL?**”). The dose of other
86 medicines may need to be adjusted when taken with NOXAFIL [for example,
87 **cyclosporine (Neoral®)**, **tacrolimus (Prograf®)**, **ritonavir**, or **atazanavir**] (see
88 “**What should I tell my doctor before taking NOXAFIL?**”).

89

90 Knowing the medicines that you are taking is important. **Tell your doctor** about all
91 the medicines you take including prescription and nonprescription medicines,

92 vitamins, and herbal supplements. Keep a list of them with you to show your doctor
93 or pharmacist. Do not take any new medicine without talking to your doctor.

94

95 **What are possible side effects of NOXAFIL®?**

96

97 The most commonly reported side effects were fever, nausea, diarrhea, vomiting,
98 and headache.

99

100 **Rarely, NOXAFIL may cause serious or life-threatening side effects. It may**
101 **also cause severe drug interactions as discussed above. Call your doctor right**
102 **away if you have any of the symptoms listed below.**

103

104 Changes in heart rate or rhythm. People who have certain heart conditions or who
105 take certain other medicines have a higher chance for this problem.

106

107 Rarely, very serious liver problems were reported in patients with serious underlying
108 medical conditions. Your doctor may test your liver function while you are taking
109 NOXAFIL. Call your doctor if you have any of these symptoms, as these may be
110 signs of liver problems: you have itching, your eyes or skin turn yellow, you feel
111 more tired than usual or feel like you have the flu, or you have nausea or vomiting.

112

113 Rarely, an increase in blood clots may occur in patients with blood cancers or post-
114 stem cell transplantation. These events may or may not be further increased in
115 patients also on posaconazole and primarily occurred in patients also receiving
116 cyclosporine or tacrolimus. If you notice swelling of one leg or shortness of breath,
117 notify your doctor immediately.

118

119 These are not all the side effects associated with NOXAFIL. For more information,
120 ask your doctor or pharmacist. If you experience any unusual effects while taking
121 NOXAFIL, contact your doctor immediately.

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124 **How do I take NOXAFIL®?**

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- 126 • NOXAFIL comes in cherry-flavored liquid form. Shake NOXAFIL Oral
127 Suspension well before use.
- 128 • Take NOXAFIL for as long as your doctor tells you. Take each dose of
129 NOXAFIL during or immediately (i.e., within 20 minutes) following a full meal.
130 In patients who cannot eat a full meal, each dose of NOXAFIL should be
131 administered with a liquid nutritional supplement Alternatively, NOXAFIL may
132 be taken with or an acidic carbonated beverage (e.g., ginger ale).
- 133 • Follow your doctor's instructions on how much NOXAFIL you should take and
134 when.

135

136 If you miss a dose of NOXAFIL, take it as soon as you remember.

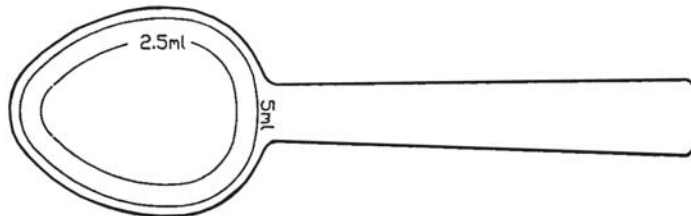
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- 139
- If you take too much NOXAFIL, call your doctor or poison control center immediately.
 - Tell your doctor right away if you develop severe diarrhea or vomiting.
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- 141

142 A measured dosing spoon is provided, marked for doses of 2.5 mL and 5 mL.

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148 It is recommended that the spoon is rinsed with water after each administration and
149 before storage.

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152 **How do I store NOXAFIL[®]?**

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- **Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F) [see USP Controlled Room Temperature]. DO NOT FREEZE. Keep all containers tightly closed.**
 - **Keep NOXAFIL, as well as other medicines, out of the reach of children.**
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160 **General information about NOXAFIL[®]**

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162 Doctors can prescribe medicines for conditions that are not in this leaflet. Use
163 NOXAFIL only as directed by your doctor. Do not give it to other people, even if they
164 have the same symptoms as you. It may harm them.

165

166 This leaflet gives the most important information about NOXAFIL. For more
167 information, talk to your doctor. You can ask your doctor or pharmacist for
168 information about NOXAFIL that is written for health care professionals.

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171

172 **What is in NOXAFIL[®]?**

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174 Active ingredient: posaconazole.

175 Inactive ingredients: polysorbate 80, simethicone, sodium benzoate, sodium citrate
176 dihydrate, citric acid monohydrate, glycerin, xanthan gum, liquid glucose, titanium
177 dioxide, artificial cherry flavor, and purified water.

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179

180 Schering Corporation, a subsidiary of **MERCK & CO., INC.**, Whitehouse Station, NJ
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182

183 **Rx only**

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188 U.S. Patent Nos. 5,661,151; 5,703,079; and 6,958,337.

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