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Patient Information About INVIRASE (in-ver-ase)

INVIRASE[®]

(saquinavir mesylate) Capsules

Generic Name: Saquinavir mesylate (sa-KWIN-a-veer mes-il-late)

ALERT: Find out about medicines that should NOT be taken with INVIRASE.
Please also read the section **MEDICINES YOU SHOULD NOT TAKE WITH INVIRASE.**

Please read this product information carefully before you start taking INVIRASE and each time you renew your prescription. There may be new information. Reading this information can help you take this medicine correctly. However, it is not a substitute for your doctor's advice about the safety and benefits of INVIRASE. You should talk to your doctor about INVIRASE as part of your long-term treatment plan for HIV before you start taking your medication and ask any questions you may have at regular checkups. Remember, you should remain under a doctor's care when using INVIRASE and should not change or stop your therapy without talking to your doctor first.

What is INVIRASE?

INVIRASE belongs to a class of anti-HIV medicines called protease (PRO-tee-ase) inhibitors. INVIRASE Capsules in combination with other anti-HIV drugs are used for the treatment of HIV, the virus that causes AIDS (acquired immunodeficiency syndrome).

How does INVIRASE work?

INVIRASE fights HIV as it grows inside cells by blocking an enzyme (protease) that HIV needs to reproduce.

INVIRASE® (saquinavir mesylate)

25 *How is INVIRASE different from FORTOVASE® (saquinavir)?*

26 Both INVIRASE and FORTOVASE contain the same active ingredient—saquinavir.
27 When INVIRASE or FORTOVASE are taken two times a day with ritonavir, a similar
28 amount of saquinavir gets into the blood to fight HIV. However, FORTOVASE can be
29 taken three times a day without ritonavir and the correct amount of saquinavir can get
30 into the blood.

31 INVIRASE should never be taken without ritonavir. FORTOVASE may be taken without
32 ritonavir if you are not able to tolerate even a small amount of ritonavir.

33 You should not substitute one for the other. If the medicine you receive does not look like
34 the light brown and green capsule (INVIRASE) it is not the right drug. Talk to your
35 doctor, nurse or pharmacist if you are not sure that you have the right medication.

36 *Who should not take INVIRASE?*

37 Anyone who has had a severe allergic reaction to INVIRASE or any of the ingredients in
38 the capsule should not take it. The use of INVIRASE in patients under 16 years of age,
39 over 65 years of age, or patients with severe liver problems has not been fully
40 investigated.

41 *How should INVIRASE/Norvir® (ritonavir) be taken?*

- 42 • The recommended dosage of INVIRASE in combination with Norvir® (ritonavir) is
43 INVIRASE 5 capsules twice a day taken with 1 capsule of Norvir twice a day. In
44 some combinations, your dose may change.
- 45 • INVIRASE must be taken along with Norvir (ritonavir).
- 46 • INVIRASE must be taken with meals or up to 2 hours after a meal—but it is easiest
47 to remember if you take it with your meals. When INVIRASE is taken without food,
48 the amount of INVIRASE in the blood is lower and may not fight HIV as well.
- 49 • When taking INVIRASE and other anti-HIV medicines, it is very important to follow
50 the directions exactly and take your medication every day. If you skip doses—or take
51 less than the prescribed dose—the medicine will not work as well, and your disease
52 could get worse.
 - 53 – If you miss a dose, you should take the next dose as soon as possible. However,
54 do not double the dose.

55 *What results have been seen with INVIRASE?*

56 INVIRASE with ritonavir has been shown to reduce the amount of virus in the blood
57 (“viral load”) and increase CD₄ (T) cells when taken with other HIV therapy.

58 *What are the side effects of INVIRASE?*

59 People treated with INVIRASE in combination with Norvir may have side effects. The
60 majority of these have been described as mild. In clinical studies of patients who received
61 saquinavir in combination with Norvir and other HIV drugs the side effects seen most

INVIRASE® (saquinavir mesylate)

62 often were: body fat change (5.4%), nausea (10.8%), vomiting (7.4%), diarrhea (6.8%),
63 stomach pain (6.1%), tiredness (6.1%), and pneumonia (5.4%).

64 Diabetes (new onset or exacerbation) and increased blood sugar levels have been reported
65 with the use of protease inhibitors. In addition, increased bleeding in patients with
66 hemophilia has also been associated with these drugs.

67 When saquinavir is taken with ritonavir, some patients may experience large increases in
68 triglyceride and lipid levels. The long-term chance of getting complications such as heart
69 attack and stroke due to increases in triglyceride and cholesterol caused by protease
70 inhibitors is not known at this time.

71 Changes in body fat have been seen in some patients taking anti-HIV medications. These
72 changes may include increased amount of fat in the upper back and neck (“buffalo
73 hump”), breasts, and around the trunk. Loss of fat from the legs and arms may also
74 happen. The cause and long-term health effects of these conditions are not known at this
75 time.

76 These are not the only side effects that can occur with INVIRASE. Your doctor can
77 discuss with you a more complete list of side effects and laboratory abnormalities that
78 may accompany this medication.

79 If any side effects or unusual symptoms do occur, contact your doctor immediately. Do
80 not stop or decrease your dose on your own. Lowering the dose may make INVIRASE
81 less effective in fighting HIV.

82 ***Are there other medications that I should not take with INVIRASE/Norvir*** 83 ***(ritonavir)?***

84 There are some drugs that should not be taken with INVIRASE. Before starting therapy with
85 INVIRASE, be sure to tell your doctor all of the medicines—prescription medications, as well
86 as over-the-counter drugs and nutritional supplements—that you are now taking or plan to
87 take.

88 ***MEDICINES YOU SHOULD NOT TAKE WITH INVIRASE***

Drug Class	Drugs Within Class Not to Be Taken with INVIRASE/Norvir (ritonavir)
Antihistamines	Seldane® (terfenadine)*, Hismanal® (astemizole)*
Antimigraines	Ergot medications (eg, Wigraine® and Cafergot®)
GI motility agents	Propulsid® (cisapride)*
Sedatives, hypnotics	Versed® (midazolam), Halcion® (triazolam)
Antimycobacterial agents	Rifampin
Neuroleptics	Pimozide

89 * No longer sold in the US.

90 INVIRASE causes increased blood levels of these compounds. This can lead to serious or
91 life-threatening reactions such as irregular heartbeat or prolonged sedation.

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92 Taking INVIRASE with St. John's wort (*hypericum perforatum*), an herbal product sold
93 as a dietary supplement, or products containing St. John's wort is not recommended. Talk
94 with your doctor if you are taking or are planning to take St. John's wort. Taking St.
95 John's wort may decrease INVIRASE levels and lead to increased viral load and possible
96 resistance to INVIRASE or cross-resistance to other antiretroviral drugs.

97 Garlic capsules should not be used while taking FORTOVASE as the sole protease
98 inhibitor due to the risk of decreased saquinavir in the blood. No data are available for the
99 co-administration of FORTOVASE and Norvir with garlic capsules or INVIRASE and
100 Norvir with garlic capsules.

101 Your doctor may want to change your medicine if you are taking rifampin (known as
102 Rifadin®, Rifamate®, Rifater® or Rimactane®) or Mycobutin® (rifabutin); these drugs
103 substantially reduce the level of INVIRASE in the blood.

104 The following drugs increase blood levels of INVIRASE: Norvir® (ritonavir)‡, Viracept®
105 (nelfinavir)§, Rescriptor® (delavirdine)§||, Nizoral® (ketoconazole), Crixivan® (indinavir)§
106 and Biaxin® (clarithromycin).

107 Talk to your doctor if you are taking lipid (cholesterol) lowering drugs and Viagra®
108 (sildenafil citrate), Levitra® (vardenafil), and Cialis® (tadalafil).

109 *Does INVIRASE cure HIV/AIDS?*

110 INVIRASE does not cure AIDS, and it does not prevent you from getting other illnesses
111 that result from advanced HIV infection. In addition, INVIRASE has not been shown to
112 reduce the risk that you may transmit HIV to others through sexual contact or infected
113 blood. You must continue to follow all of your doctor's recommendations for managing
114 your illness.

115 *What else should I discuss with my doctor?*

116 Inform your doctor:

- 117 • If you are pregnant or become pregnant while taking INVIRASE. The effects of
118 INVIRASE on pregnant women or unborn babies are not yet fully known. In
119 addition, experts advise against breast-feeding if you are HIV positive, to reduce the
120 risk of passing the virus to your baby.
- 121 • If you are taking anti-HIV medications. Your doctor may want to change one or more
122 of your anti-HIV drugs in order to achieve the best results when you start treatment with
123 INVIRASE.
- 124 • If you have diabetes or a family history of diabetes, or if you have hemophilia,
125 hepatitis or other liver disease, your doctor should decide if INVIRASE is right for
126 you.
- 127 • If you have ever taken FORTOVASE, discuss with your doctor whether INVIRASE
128 is right for you.

INVIRASE® (saquinavir mesylate)

129 ***How is INVIRASE supplied?***

130 INVIRASE is available as light brown and green capsules in a 200-mg strength.
131 INVIRASE comes in bottles of 270 capsules.

132 ***How should I store INVIRASE?***

133 INVIRASE capsules should be stored at room temperature 59° to 86° F (15° to 30°C). The
134 bottles should be kept tightly closed.

135 INVIRASE has been prescribed specifically for you, and only for a particular condition.
136 Do not use it for anything else. Do not give it to anyone else. If you think you have taken
137 more than your prescribed dose, seek medical attention.

138 **Keep this medication and all other medications out of the reach of children.** Do not
139 keep medicine that is out of date or that you no longer need. Be sure that if you throw any
140 medicine away, it is out of the reach of children.

141 This provides only a brief summary of product information about INVIRASE. If you
142 have any questions about INVIRASE or HIV, talk to your doctor.

143 † Below the amount that could be found using a standard test.

144 ‡ Dosages greater than 100 mg twice a day of ritonavir when taken in combination with
145 saquinavir were associated with an increase in side effects.

146 § The safety and efficacy of INVIRASE in combination with these drugs has not been
147 established. Dosage adjustments may be required.

148 || Use of this combination should be accompanied by close monitoring of liver
149 enzymes.

150 FORTOVASE and Versed are registered trademarks of Hoffmann-La Roche Inc. Norvir
151 and Biaxin are registered trademarks of Abbott Laboratories. Halcion, Mycobutin and
152 Rescriptor are registered trademarks of Pharmacia & Upjohn Co. Hismanal, Propulsid
153 and Nizoral are registered trademarks of Janssen Pharmaceutica Inc. Seldane, Rifadin,
154 Rifamate and Rifater are registered trademarks of Hoechst Marion Roussel. Rimactane
155 and Cafergot are registered trademarks of Novartis Pharmaceuticals Corporation.
156 Viracept is a registered trademark of Agouron Pharmaceuticals Inc. Crixivan is a
157 registered trademark of Merck & Co., Inc. Viagra is a registered trademark of Pfizer, Inc.
158 Levitra is a registered trademark of Bayer Pharmaceuticals Corp. Cialis is a registered
159 trademark of Eli Lilly and Company.

160 *If you have any questions about INVIRASE, call toll free at 1-800-910-4687.*

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163 Revised: December 2003

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