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Patient Information About INVIRASE (in-ver-ase)

INVIRASE

(saquinavir mesylate)

CAPSULES and TABLETS

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

Rx only

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 and Tablets 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.

Who should not take INVIRASE?

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

How should INVIRASE/Norvir (ritonavir) be taken?

- The recommended dosage of INVIRASE in combination with Norvir® (ritonavir) is INVIRASE 5 capsules or 2 tablets twice a day taken with 1 capsule of Norvir twice a day. In some combinations, your dose may change.

- 36 • INVIRASE must be taken along with Norvir (ritonavir).
- 37 • INVIRASE must be taken with meals or up to 2 hours after a meal—but it is easiest
38 to remember if you take it with your meals. When INVIRASE is taken without food,
39 the amount of INVIRASE in the blood is lower and may not fight HIV as well.
- 40 • When taking INVIRASE and other anti-HIV medicines, it is very important to follow
41 the directions exactly and take your medication every day. If you skip doses—or take
42 less than the prescribed dose—the medicine will not work as well, and your disease
43 could get worse.
- 44 – If you miss a dose, you should take the next dose as soon as possible. However,
45 do not double the dose.

46 **What results have been seen with INVIRASE?**

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

49 **What are the side effects of INVIRASE?**

50 People treated with INVIRASE in combination with Norvir may have side effects. The
51 majority of these have been described as mild. In clinical studies of patients who received
52 saquinavir in combination with Norvir and other HIV drugs the side effects seen most
53 often were: body fat change (5.4%), nausea (10.8%), vomiting (7.4%), diarrhea (8.1%),
54 stomach pain (6.1%), tiredness (6.1%), and pneumonia (5.4%).

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

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

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

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

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

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

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

79 **Medicines you should not take with INVIRASE**

Drug Class	Drugs Within Class Not to Be Taken with INVIRASE/Norvir (ritonavir)
Antiarrhythmics	Pacerone (amiodarone), Tambocor (flecainide), Rhythmol (propafenone), bepridil, quinidine
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

80 * No longer sold in the US.

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

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

88 No data are available for the coadministration of INVIRASE and Norvir with garlic
 89 capsules. Garlic capsules should not be used while taking saquinavir due to the potential
 90 for garlic capsules to decrease the amount of saquinavir in the blood.

91 Your doctor may want to change your medicine if you are taking rifampin (known as
 92 Rifadin®, Rifamate®, Rifater® or Rimactane®) or Mycobutin® (rifabutin); these drugs
 93 substantially reduce the level of INVIRASE in the blood. Rifampin, in combination with
 94 INVIRASE and ritonavir, may also cause severe liver problems.

95 Caution should be exercised when taking INVIRASE with digoxin. Your doctor may
 96 want to decrease the dose of digoxin and monitor the levels of digoxin in your blood.

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

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

102 **Does INVIRASE cure HIV/AIDS?**

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

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

109 Inform your doctor:

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

122 **How is INVIRASE supplied?**

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

125 INVIRASE is also available as light orange to greyish- or brownish-orange tablets in a
126 500-mg strength. INVIRASE comes in bottles of 120 tablets.

127 **How should I store INVIRASE?**

128 INVIRASE capsules and tablets should be stored at room temperature. The bottles should be
129 kept tightly closed.

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

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

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

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

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

142 || Use of this combination should be accompanied by close monitoring of liver
143 enzymes.

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

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