

Medication Guide

**INVIRASE® (in-ver-ase)
(saquinavir mesylate)
capsules**

**INVIRASE® (in-ver-ase)
(saquinavir mesylate)
tablets**

Important: Ask your healthcare provider or pharmacist about medicines that should not be taken with INVIRASE. For more information, see the section “Who should not take INVIRASE?”

Read this Medication Guide before you start taking INVIRASE and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment. You and your healthcare provider should talk about your treatment with INVIRASE before you start taking it and at regular checkups. You should stay under a healthcare provider’s care when taking INVIRASE.

Also read the Medication Guide for ritonavir (NORVIR).

What is the most important information I should know about INVIRASE?

- **INVIRASE must be taken along with ritonavir (NORVIR).**
- **INVIRASE should not be taken along with cobicistat (TYBOST®).**

INVIRASE may cause serious side effects including:

- **Interactions with other medicines.** It is important to know the medicines that should not be taken with INVIRASE. Read the section “What should I tell my healthcare provider before taking INVIRASE?”
- **Changes in your heart rhythm and the electrical activity of your heart.** These changes may be seen on an EKG (electrocardiogram) and can lead to serious heart problems. Your risk for these problems may be higher if you:
 - already have a history of abnormal heart rhythm, including Congenital Long QT Syndrome, or other types of heart disease.
 - take other medicines that can affect your heart rhythm while you take INVIRASE.

Tell your healthcare provider right away if you have any of these symptoms while taking INVIRASE:

- dizziness
- fainting
- lightheadedness
- sensation of abnormal heartbeats

See the section below “What are the possible side effects of INVIRASE?” for more information about serious side effects.

What is INVIRASE?

INVIRASE is a prescription HIV-1 (Human Immunodeficiency Virus) medicine used with ritonavir and other antiretroviral medicines to treat HIV-1 in people over 16 years of age.

HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

In children, INVIRASE doses that are both effective and safe could not be determined.

When used with other antiretroviral medicines to treat HIV-1, INVIRASE may help:

- reduce the amount of HIV-1 in your blood.
- increase the number of white blood cells called CD4+ (T) cells in your blood which help fight off other infections.

Reducing the amount of HIV-1 and increasing the CD4+ (T) cells in your blood may help improve your immune system.

This may reduce your risk of death or getting infections that can happen when your immune system is weak (opportunistic infections.)

INVIRASE does not cure HIV infection or AIDS. You must stay on continuous HIV therapy to control HIV infection and decrease HIV-related illnesses.

Avoid doing things that can spread HIV-1 infection to others:

- Do not share or re-use needles or other injection equipment.
- Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.
- Do not have any kind of sex without protection. Always practice safer sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

Ask your healthcare provider if you have any questions about how to prevent passing HIV-1 to other people.

Who should not take INVIRASE?

Do not take INVIRASE if you have the following conditions:

- a condition called Congenital Long QT Syndrome.
- complete AV (atrioventricular) heart block and you do not have a pacemaker or you are at risk for complete AV heart block.
- low potassium or low magnesium in your blood.

- severe liver problems.
- you have had a severe allergic reaction to saquinavir mesylate or any of the ingredients in INVIRASE. See the end of this Medication Guide for a complete list of ingredients in INVIRASE.

Talk to your healthcare provider before taking INVIRASE if you have any of the conditions listed above.

Taking INVIRASE with certain other medicines can cause serious problems or life threatening reactions.

Do not take INVIRASE with ritonavir (NORVIR) if you take any of the following medicines:

- alfuzosin (Uroxatral[®])
- amiodarone (Cordarone[®], Pacerone[®])
- atazanavir (Revataz[®])
- bepridil
- cisapride
- clarithromycin (Biaxin[®])
- clozapine (Clozaril[®])
- dapsons
- dofetilide (Tikosyn[®])
- disopyramide (Norpace[®])
- Ergot containing medicines, including:
 - dihydroergotamine mesylate (D.H.E. 45, Embolex, Migranal)
 - ergonovine, ergonovine and methylergonovine (Ergorate, Methergine), ergotamine and methylergonovine
 - ergotamine tartrate (Cafergot, Migergot, Ergomar, Ergostate Medihaler Ergotamine, Wigraine Wigrettes)
- erythromycin
- flecainide (Tambocor[®])
- halofantrine
- haloperidol (Haldol[®])
- lidocaine
- lovastatin (Advicor[®], Altoprev[®], Mevacor[®])
- midazolam hydrochloride oral syrup
- pentamidine (Nebupent[®], Pentam[®] 300)
- Phenothiazine containing medicines, including:
 - chlorpromazine
 - mesoridazine
 - thioridazine
- pimozide (Orap[®])
- propafenone (Rhythmol[®])
- quinidine
- quinine (Qualaquin[®])
- rifampin (Rifadin[®], Rifamate[®], Rifater[®], Rimactane[®])
- sildenafil (Revatio[®])
- simvastatin (Simcor[®], Vytorin[®], Zocor[®])
- tacrolimus (Prograf[®])
- trazodone (Oleptro[®])
- triazolam (Halcion[®])
- ziprasidone

Talk to your healthcare provider before taking INVIRASE if you take any of the medicines listed above.

What should I tell my healthcare provider before taking INVIRASE?

Before taking INVIRASE, tell your healthcare provider about all of your medical conditions, including if you:

- have any heart problems, including a condition called Congenital Long QT Syndrome.
 - have diabetes.
 - have liver problems, including Hepatitis B or Hepatitis C.
 - have hemophilia. People who take INVIRASE may have increased bleeding.
 - are pregnant or plan to become pregnant. It is not known if INVIRASE will harm your unborn baby.
- Pregnancy Registry:** There is a pregnancy registry for women who take antiretroviral medicines during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your healthcare

provider about how you can take part in this registry.

- are breastfeeding or plan to breastfeed. You should not breastfeed if you have HIV because of the risk of passing HIV to your baby. **Do not breastfeed if you take INVIRASE.** We do not know if INVIRASE can be passed to your baby in your breast milk and whether it could harm your baby. Talk to your healthcare provider about the best way to feed your baby.

Tell your healthcare provider about all the medicines you take, including prescriptions and over-the-counter medicines, vitamins and herbal supplements. Tell your healthcare provider if you take St. John's wort.

INVIRASE may affect the way other medicines work, and other medicines may affect how INVIRASE works. Do not start taking a new medicine without talking with your healthcare provider or pharmacist. Your healthcare provider can tell you if it is safe to take INVIRASE with other medicines.

How should I take INVIRASE?

- Take INVIRASE exactly as your healthcare provider tells you.
- INVIRASE comes as a 500 mg tablet or a 200 mg capsule.
- Do not change your dose of INVIRASE or stop treatment without first talking with your healthcare provider. Stay under the care of your healthcare provider during treatment with INVIRASE.
- INVIRASE must be used along with ritonavir (NORVIR).
- Take INVIRASE up to 2 hours after a meal.
- Do not miss a dose of INVIRASE. It is very important to take your medicine every day. If you skip doses or take less than the prescribed dose the medicine will not work as well, and the virus may become harder to treat.
- If you miss a dose of INVIRASE, you should take the next dose as soon as possible. Do not double your dose.
- If you take too much INVIRASE, call your healthcare provider or go to the nearest hospital emergency room right away.
- If you are unable to swallow INVIRASE capsules whole, you may open the capsule and mix the contents with sugar syrup or jam. People with type 1 diabetes or glucose intolerance should use sorbitol syrup.
 - Use a medicine cup to measure 15 mL of the syrup or jam into a container. You can ask your pharmacist for a medicine cup if you do not have one.
 - Open the capsule and pour the contents into the container with the syrup or jam.
 - Mix with a spoon for 30 to 60 seconds.
 - Let the mixture come to room temperature.
 - Eat the entire mixture. Be sure to take the full dose.

What are the possible side effects of INVIRASE?

INVIRASE can cause serious side effects.

- See “What is the most important information I should know about INVIRASE?”
- **Diabetes and high blood sugar.** Some people who take protease inhibitors including INVIRASE get new or more serious diabetes, or high blood sugar. Tell your healthcare provider if you notice an increase in thirst or urinate more often than normal while taking INVIRASE.
- **Liver problems.** People with liver problems such as Hepatitis B or C, cirrhosis or have a history of alcoholism may have worsening liver problems. Tell your healthcare provider right away if you have any of these signs and symptoms of liver problems:
 - loss of appetite
 - yellowing of your skin or whites of your eyes (jaundice)
 - dark-colored urine
 - pale colored stools
 - itchy skin
 - stomach area (abdominal) pain
- **Increased bleeding in people with hemophilia.** Some people with hemophilia have increased bleeding with protease inhibitors including INVIRASE.
- **Increase in certain fat (cholesterol and triglycerides) levels in your blood.** Your healthcare provider will check your blood for high levels of cholesterol and triglycerides before you start INVIRASE and during treatment with INVIRASE.
- **Changes in body fat** can happen in people who take HIV medicine. These changes may include increased amount of fat in the upper back and neck (“buffalo hump”), breasts, and around the middle of your body (trunk). Loss of fat from the legs, arms and face may also happen. The exact cause and long-term health effects of these conditions are not known.
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider if you start having new or worse symptoms of infection after starting your HIV medicine.

Common side effects of INVIRASE include:

- nausea
- vomiting
- diarrhea
- stomach area (abdominal) pain
- tiredness
- pneumonia
- changes in body fat

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of INVIRASE. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to Genentech at 1-800-835-2555.

How should I store INVIRASE?

- Store INVIRASE at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep INVIRASE in a tightly closed container.

Keep INVIRASE and all medicine out of the reach of children.

General information about INVIRASE.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use INVIRASE for a condition for which it was not prescribed. Do not give INVIRASE to other people even if they have the same condition you have. It may harm them.

This Medication Guide summarizes the most important information about INVIRASE. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about INVIRASE that is written for health professionals.

For more information, go to <http://www.gene.com/gene/products/information/invirase> or call 1-877-436-3683.

What are the ingredients in INVIRASE?**Active ingredient:** saquinavir mesylate**Inactive ingredients:**

200 mg Capsule: lactose, microcrystalline cellulose, povidone K30, sodium starch glycolate, talc, and magnesium stearate. Capsule shell: gelatin and water with the following dye systems: red iron oxide, yellow iron oxide, black iron oxide, FD&C Blue #2, and titanium dioxide.

500 mg Tablet: lactose, microcrystalline cellulose, povidone K30, croscarmellose sodium, and magnesium stearate.

Film coat: hypromellose, titanium dioxide, talc, iron oxide yellow, iron oxide red, and triacetin.

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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