

Consumer Medicine Information

Ask your doctor if you have any questions why INVIRASE has been prescribed for you.

This medicine is available only with a doctor's prescription.

What is in this leaflet

This leaflet answers some common questions about INVIRASE capsules and film-coated tablets. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking INVIRASE against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What INVIRASE is used for

INVIRASE belongs to a group of medicines called anti-HIV drugs. Within this group, INVIRASE belongs to a class of drugs called HIV protease inhibitors. INVIRASE is used for the treatment of HIV (Human Immunodeficiency Virus). It works by interfering with the viral reproductive cycle.

INVIRASE should be used only in combination with zidovudine (Zidovudine[®]) and other medicines to treat the HIV virus.

Please note that you should always report any changes in your condition to your doctor to ensure that any infections which occur due to your low immunity (called opportunistic infections) are treated promptly.

Your doctor may have prescribed INVIRASE for another purpose.

Before you take INVIRASE

When you must not take it

Do not take INVIRASE if:

- 1. you have allergies to INVIRASE or any ingredients listed at the end of this leaflet**
- 2. you have allergies to ritonavir**
- 3. you have severe liver disease**
- 4. if you were born with or have**
 - any condition with abnormal electrocardiograms (ECG- electrical recording of the heart)
 - a salt imbalance in the blood, especially low concentrations of potassium (hypokalaemia) which are currently not corrected by treatment
 - a very slow heart rate
 - a weak heart (heart failure)
- 5. you are taking medicines that cause abnormal ECG changes**

These medicines include:

 - certain heart medicines (amiodarone, bepridil, dofetilide, flecainide, hydroquinidine, ibutilide, lidocaine, propafenone, quinidine, sotalol)
 - medicines to treat depression (trazodone)
 - certain anti-infectives (e.g. erythromycin,)
 - terfenadine and astemizole; medicines used to treat allergic conditions (antihistamines)

- cisapride, a medicine used to treat stomach reflux.
- pimozone, a medicine used to treat psychoses
- methadone, a medicine used to treat opioid dependence

6. you are taking certain other medicines

These medicines include:

- ergotamine, dihydroergotamine, ergonovine, methylegonovine, and methysergide; medicines used to treat migraine headaches
 - oral midazolam and triazolam; medicines to help you sleep at night or before surgery
 - simvastatin, lovastatin, atorvastatin, cerivastatin and fluvastatin; medicines used to lower cholesterol levels in the blood
 - rifampicin; a medicine used to prevent or treat tuberculosis
 - tipranavir; lopinavir/ritonavir combination, medicines used to treat people infected with HIV
- 7. the package is torn or shows signs of tampering**
- 8. the expiry date (EXP) printed on the pack has passed**
- If you take it after the expiry date has passed, it may not work as well.

If you are not sure if you should be taking INVIRASE, talk to your doctor.

Do not give INVIRASE to children less than 12 years of age.

Safety and effectiveness in younger children have not been established.

Before you start to take it

Your doctor must know all about the following before you start to take INVIRASE.

- 1. if you are pregnant or plan to become pregnant**

It is not known whether INVIRASE is harmful to an

unborn baby when taken by a pregnant woman. If there is a need to take INVIRASE when you are pregnant your doctor will discuss the risks and benefits to you and the unborn baby.

2. if you are breast-feeding or plan to breast-feed

It is not known whether INVIRASE passes into breast milk. Your doctor will decide whether or not you should breast-feed.

3. if you are allergic to any other medicines, foods, dyes or preservatives

4. If you have a history of

- arrhythmias, or abnormal heart rhythms
- angina or heart disease caused by reduced blood flow in the blood vessels of the heart muscle
- a disease of heart muscle

INVIRASE can change your heart's ECG. This is more common if you are female or elderly.

If you experience palpitations or any changes in your heart rate during treatment, you should tell your doctor immediately. Your doctor may wish to perform an ECG to measure your heart rhythm.

5. you have hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption (autosomal recessive disorder)

INVIRASE tablets contain lactose

6. if you have any other health problems including:

- kidney disease
- liver disease
- haemophilia (a condition where patients have a tendency to bruise and bleed easily)
- diabetes or high blood sugar levels
- high cholesterol levels and high triglyceride levels, a blood fat

- diarrhoea

If you have not told your doctor about any of the above, tell them before you take INVIRASE.

Taking other medicines

Tell your doctor if you are taking any other medicines including any that you have bought without a prescription from a pharmacy, supermarket or health food shop.

INVIRASE may be taken with a number of other medications that are commonly used in HIV infection.

There are some medicines that **must not be taken** with INVIRASE (see "Before you take INVIRASE" above). Other medicines may interfere with INVIRASE. These include:

- itraconazole, ketoconazole, miconazole and fluconazole; medicines used to treat fungal infections
- carbamazepine, phenobarbitone and phenytoin; medicines used to treat epilepsy
- Felodipine, nifedipine, nicardipine, diltiazem, nimodipine, verapamil, amlodipine, nisoldipine, isradipine: calcium channel blockers used to treat heart conditions
- certain heart or blood pressure medicines
- midazolam (intravenous), medicine to help you sleep at night or before surgery
- antibiotics such as clarithromycin, clindamycin, azithromycin, quinupristin/dalfopristin, rifabutin;
- omeprazole, esomeprazole, pantoprazole, lansoprazole, rabeprazole; medicines used to treat diseases related to the acid in the stomach

- cimetidine, nizatidine; medicines used to treat diseases related to excess acid in the stomach
 - St John's wort (hypericum perforatum) which is a herbal product
 - garlic capsules
 - indinavir, delavirdine, didanosine and efavirenz; medicines used to treat people infected with HIV
 - sildenafil, tadalafil and vardenafil; medicines used to treat erectile dysfunction
 - cyclosporin, tacrolimus and rapamycin, medicines used to suppress the immune system
 - warfarin; a medicine to prevent blood clots
 - digoxin and disopyramide; medicines used to treat fast or irregular heart rate
 - quinine; a medicine use to treat night cramps and malaria
 - dapsone; an anti-infective agent used to treat TB and leprosy
 - alfentanil and fentanyl; strong pain killers usually used in anaesthesia
 - alprazolam, diazepam, clorazepate, flurazepam; medicines used to treat anxiety
 - nefazodone, tricyclic or tetracyclic antidepressants; medicines used to treat depression
 - ethinyloestradiol, an oestrogen-based oral contraceptive
 - dexamethasone, fluticasone and budesonide; medicines which reduce the activity of the immune system or treat asthma and hay fever.
- Please consult your doctor if using intranasal or inhaled corticosteroid

These medicines may be affected by INVIRASE or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has a complete list of medicines to be careful with or avoid while taking INVIRASE.

If you have not told your doctor about any of the above, tell them before you start taking INVIRASE.

How to take INVIRASE

How much to take

Take INVIRASE only when prescribed by your doctor. Your doctor will tell you how many INVIRASE film-coated tablets to take each day.

INVIRASE should be taken only in combination with ritonavir (Norvir[®]), a medicine used to treat HIV.

The recommended dose of INVIRASE is two 500 mg film-coated tablets of INVIRASE two times a day (a total of four INVIRASE tablets per day), with one 100 mg capsule of ritonavir (Norvir[®]) two times a day (a total of two Norvir[®] capsules).

Both medicines should be taken at the same time.

How to take it

Film-coated tablets should be swallowed whole with a glass of water.

When to take it

Take INVIRASE within two hours after a meal to ensure maximum absorption and effectiveness.

Taking INVIRASE with a meal that is high in calories, fat and protein increases your body's ability to absorb the medicine and in turn increases its effectiveness.

Taking your medicine at the same time each day will have the best effect on the HIV infection. It will also help you remember to take the medicine.

How long to take INVIRASE

INVIRASE helps control your HIV infection but does not cure it. Therefore INVIRASE must be taken every day. Continue taking INVIRASE for as long as your doctor prescribes.

If you forget to take INVIRASE

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember together with some food and then go back to taking it as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not take a double a dose to make up for one you have missed.

In case of an overdose

If you think that you or anyone else may have taken too much INVIRASE, immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist. You may need urgent medical attention.

While you are taking INVIRASE

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking INVIRASE.

Do not take any other medicines whether they require a

prescription or not without first telling your doctor.

Continue to use safe sexual practices while taking INVIRASE. INVIRASE has not been shown to decrease the chance of giving HIV to your partner.

If you are using an oestrogen-based oral contraceptive, you should also use an additional type of contraception.

If you become pregnant while taking INVIRASE, tell your doctor.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel that INVIRASE is not helping your condition.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Your doctor may want to take regular blood samples to measure your blood glucose levels or liver enzymes.

Things you must not do

Do not stop taking INVIRASE or change the dose without first checking with your doctor. Do not let yourself run out of medicine over the weekend or on holidays.

Do not give INVIRASE to anyone else even if their symptoms seem similar to yours.

Things to be careful of

Be careful driving or operating machinery until you know how INVIRASE affects you.

INVIRASE generally does not cause problems with your ability to drive a car or operate machinery. However, as with many medicines, INVIRASE may cause dizziness in some people. Make sure you know how you react

to INVIRASE before you drive a car or operate machinery.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking INVIRASE.

INVIRASE helps most people with HIV infection but it may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Frequently it is difficult to tell whether side effects are the result of taking INVIRASE, effects of the HIV disease or side effects of other medicines you may be taking. For this reason it is very important to inform your doctor of any change in your condition. Your doctor may want to change your dose or advise you to stop taking INVIRASE.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- diarrhoea
- constipation
- stomach discomfort/pain, distention, wind
- vomiting,
- feeling sick
- dizziness, headache
- tiredness, weakness
- generally feeling unwell
- skin problems such as itching and rash
- hair loss
- dry mouth/lip
- heartburn, indigestion or belching after eating

- tingling, numbness, weakness of the arms or legs
- inability to sleep or increased need for sleep
- increased or decreased appetite
- taste disturbance or loss of taste
- decreased libido
- shortness of breath, difficulty breathing, chest tightness or rapid deep breathing
- muscle spasms, fits or seizures
- allergic reaction- shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin
- being short of breath when exercising
- looking pale
- yellowing of skin or eyes
- increased bruising or bleeding

These are the more common side effects of INVIRASE. For the most part these have been mild.

There are some side effects that may occur with the protease inhibitor class of drug. As mentioned earlier, INVIRASE belongs to this class of drugs, and may cause the following side effects:

- diabetes (excessive thirst, increased appetite with weight loss, feeling tired, drowsy, weak, depressed, irritable and generally unwell, and passing large amounts of urine)
- body fat distribution changes including loss of fat from the limbs and increased fat around the stomach, breast enlargement could also occur in women
- metabolic abnormalities such as hypertriglyceridemia (increased blood levels of triglycerides); insulin resistance (diminished effectiveness of insulin in lowering the levels of blood sugar); hypercholesterolemia (increased blood levels of cholesterol); and hyperlactatemia (increased levels of lactic acid in the blood)

This is not a complete list of all possible side effects. Others may

occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking INVIRASE

Storage

Keep your INVIRASE tablets in the bottle until it is time to take them. If you take them out of the bottle they may not keep well.

Keep INVIRASE in a cool dry place where the temperature stays below 30 °C. Do not store it, or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep INVIRASE where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking INVIRASE, or the INVIRASE has passed its expiry date, ask your pharmacist what to do with any tablets that are left over.

Product Description

What INVIRASE looks like

INVIRASE 500 mg film-coated tablets are light orange to brownish orange in colour and oval in shape. The tablets are marked "SQV 500" on one side and "Roche" on the other side. They come in a white plastic bottle.

This leaflet was prepared on 15 October 2010

Ingredients

Active ingredient - saquinavir

- each tablet contains 500 mg saquinavir free base as saquinavir mesylate.

Inactive ingredients -

The tablets also contain:

- lactose
- microcrystalline cellulose (460)
- croscarmellose sodium
- povidone
- magnesium stearate (470)
- hypromellose
- talc (553)
- water
- triacetin

and the colours iron oxide red (172), iron oxide yellow (172) and titanium dioxide (171).

INVIRASE film-coated tablets are gluten free.

INVIRASE 500 mg film-coated tablets come in packs of 120 tablets.

Manufacturer

INVIRASE is distributed by:

Roche Products Pty Limited
ABN 70 000 132 865
4 - 10 Inman Road
Dee Why NSW 2099

Customer enquiries: 1800 233 950

Please check with your pharmacist for the latest Consumer Medicine Information.

Australian Registration Number

- INVIRASE 500 mg film-coated tablets AUST R 119419.