

INVIRASE®

pronounced "In-vir-ase"

contains the active ingredient saquinavir

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about INVIRASE 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 must 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.

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.

INVIRASE is not a cure for HIV infection and you may continue to acquire illnesses associated with advanced HIV infection, including opportunistic infections.

INVIRASE does not reduce the risk of transmitting HIV to others through sexual contact or contamination through blood.

Before you take INVIRASE

When you must not take it

Do not take INVIRASE if:

- 1. you have allergies to saquinavir or any ingredients listed at the end of this leaflet**
- 2. you have severe liver disease**
- 3. 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)
- 4. you are taking medicines that can cause abnormal ECG changes**

These medicines include:

 - certain heart medicines such as amiodarone, bepridil, disopyramide, dofetilide, flecainide, hydroquinidine, systemic lignocaine, propafenone, and quinidine

- trazodone, a medicine to treat depression
 - clarithromycin, erythromycin and halofantrine, which are used to treat infections
 - astemizole, mizolastine and terfenadine which are medicines used to treat allergic conditions (antihistamines)
 - cisapride, a medicine used to treat stomach reflux
 - chlorpromazine, clozapine, haloperidol, pimozide, quetiapine, sertindole, thioridazine and ziprasidone which are medicines used to treat psychoses
 - trazodone, a medicine used as an antidepressant
 - atazanavir, another HIV protease inhibitor
 - tacrolimus, a medicine used to suppress your own immune system
 - quinine, a medicine use to treat night cramps and malaria
 - dapsone, a medicine used to treat leprosy
- 5. you are taking certain other medicines**
Such medicines as:
- dihydroergotamine, ergonovine ergotamine and methylergonovine which are used to treat migraine headaches
 - oral midazolam and triazolam which are used to help you sleep at night or for sedation before surgery
 - lovastatin and simvastatin which are used to lower cholesterol levels in the blood
 - rifampicin, an antibiotic used to prevent or treat certain types of bacterial infections such as tuberculosis
 - alfuzosin, a medicine used as a muscle relaxant to help with urination
- 6. the package is torn or shows signs of tampering**
- 7. 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 or pharmacist.
INVIRASE is not usually given to children less than 16 years of age.

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 irregular heart rhythms
 - a very slow heart rate (bradycardia)
 - a weak heart (heart failure)

- a disease of the heart muscle
- INVIRASE can change your heart's ECG (a test to check your heart rhythm ie electrocardiogram). 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. if 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:**

- liver disease
- kidney 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 or pharmacist if you are taking ANY other medicines including any that you have bought without a prescription from a pharmacy, supermarket or health food shop.

There are some medicines that CANNOT BE TAKEN with INVIRASE (see "Before you take INVIRASE" above).

Other medicines may interfere with INVIRASE and your doctor may need to adjust the dose and/or monitor you more closely if you continue to take them. These include:

- medicines used to treat fungal infections such as fluconazole, itraconazole, ketoconazole and miconazole
- medicines used to treat epilepsy such as carbamazepine, phenobarbitone and phenytoin
- medicines used to treat heart conditions called calcium channel blockers such as amlodipine, diltiazem, felodipine, isradipine, nifedipine, nifedipine, nimodipine, nisoldipine and verapamil
- certain heart or blood pressure medicines
- medicine to help you sleep at night or sedate you before surgery such as intravenous midazolam
- antibiotics such as fusidic acid, pentamidine, quinupristin/dalfopristin, rifabutin and sparflaxacin
- medicines used to treat diseases related to the acid in the stomach such as esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole and ranitidine
- St John's wort (*Hypericum perforatum*) which is a herbal product
- garlic capsules
- grapefruit juice

- medicines used to treat HIV infection such as delavirdine, didanosine, tenofovir disoproxil fumarate, efavirenz, enfuvirtide, fosamprenavir, indinavir, lopinavir, maraviroc, nelfinavir, nevirapine, tenofovir disoproxil, tipranavir, zalcitabine and/or zidovudine
- medicines used to treat erectile dysfunction such as sildenafil, tadalafil and vardenafil
- medicines used to suppress the immune system such as cyclosporin and rapamycin.
- colchicine; a gout medication.
- warfarin; a medicine to prevent blood clots
- medicines used to treat heart-related conditions such as digoxin, ibutilide, sotalol and vincamine i.v.
- strong pain killers usually used in anaesthesia such as alfentanil and fentanyl
- medicines used to treat anxiety such as alprazolam, clorazepate, diazepam and flurazepam
- medicines used to treat depression such as nefazodone, tricyclic or tetracyclic antidepressants such as clomipramine or maprotiline
- ethinylloestradiol based oral contraceptives
- medicines to treat asthma and hay fever such as budesonide, dexamethasone, fluticasone and salmeterol.
- bosentan; a medicines used to treat pulmonary arterial hypertension
- medicines used to lower cholesterol such as atorvastatin, cerivastatin, fluvastatin and pravastatin
- methadone; a medicine used to treat opioid dependence

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 or pharmacist about any of the above, or any other medicines you are taking, 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 only be taken only in combination with ritonavir (Norvir®), a medicine used to treat HIV.

The recommended 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).

If you have not received treatment before, the recommended starting dose of INVIRASE is one 500 mg film-coated tablet twice a day (total of two INVIRASE tablets a day) with one 100 mg capsule of ritonavir (Norvir®) two times a day (a total of two Norvir® capsules) for the first 7 days of treatment. After 7 days 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).

If you are switching from another treatment the recommended dose 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

Tablets should be swallowed whole with a glass of water.

When to take it

Take INVIRASE tablets 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 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 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 your doctor's advice. 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, 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.

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 or feeling sick
- dizziness, headache
- tiredness, weakness
- generally feeling unwell
- skin problems such as itching and rash
- hair loss
- dry mouth/lips
- 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 (sex drive)
- 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 HIV the protease inhibitor class of drug. As mentioned above, 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)
- Within the first few weeks of treatment with anti-HIV medicines, some people, may experience a worsening of an infection that is being treated or experience new infections or may develop inflammatory reactions (e.g. pain, redness, swelling, high temperature) which may resemble an infection and may be severe. It is thought that these reactions are caused by a recovery in the body's ability to fight infections, previously suppressed by HIV. If you become concerned about any new symptoms, or any changes in your health, please discuss with your doctor immediately

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 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.

Ingredients

Active ingredient - saquinavir

- each tablet contains 500 mg saquinavir as saquinavir mesylate.

Inactive ingredients

- lactose
- microcrystalline cellulose (460)
- croscarmellose sodium
- povidone
- magnesium stearate (470)
- hypromellose
- talc (553)
- water
- triacetin
- colourants, iron oxide red (172), iron oxide yellow (172) and titanium dioxide (171).

INVIRASE tablets are gluten free.

INVIRASE 500 mg 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 tablets AUST R 119419.

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