

INVIRASE[®] CAPSULE/FILM-COATED TABLET

Saquinavir mesylate (200mg and 500mg)

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What Invirase is used for

Invirase contains the active ingredient *saquinavir mesylate*.

Invirase is used to treat the Human Immunodeficiency Virus (HIV). Invirase should only be used in combination with zidovudine and other medicines used to treat HIV.

Invirase is available only with a doctor's prescription

How Invirase works

The medicine contained within Invirase, saquinavir mesylate, belongs to a group of medicines called antiviral agents. Within this group, Invirase belongs to a class of medicines known as HIV Protease Inhibitors. It works by interfering with the viral reproductive cycle.

Before you take Invirase

When you must not take it

Do not take Invirase if:

1. You are allergic to Invirase, zidovudine or any other ingredients listed at the end of this leaflet.
2. You are on medicines that cause abnormal ECG change of the heart such as:
 - certain heart medicines (amiodarone, bepridil, flecainide, lidocaine, propafenone, quinidine)
 - certain anti-infectives
 - terfenadine and astemizole and other antihistamines (medicines to treat allergic conditions)
 - cisapride (a medicine used to treat stomach reflux)

- pimozone (a medicine used to treat psychosis)
3. You have severe liver disease
 4. You were born with or have:
 - any condition with abnormal electrocardiogram (ECG – electrical recordings of the heart)
 - an imbalance of salt concentrations in the blood, such as low levels of potassium, which is currently not corrected by any treatment
 - a very slow heart rate
 - a weak heart (heart failure)
 5. You are taking certain other medicines, including:
 - medicines used to treat migraine headaches (ergotamine, dihydroergotamine, ergonovine, methylergonovine)
 - medicines to help you sleep at night or before surgery (triazolam, midazolam)
 - medicines to lower cholesterol levels in the blood (simvastatin, lovastatin)
 - a medicine used to prevent or treat tuberculosis (rifampicin)
 6. The packaging is torn or shows signs of tampering
 7. The expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure if you should start taking Invirase, contact your doctor. Do not give Invirase to children below 16 years of age. There is limited information on the use of Invirase in younger children.

Before you start to take it

You must tell your doctor if:

1. You are pregnant or plan to become pregnant.

It is not known whether Invirase can cause harm to your unborn baby while you are pregnant. If there is a need to take Invirase while you are pregnant, your doctor will discuss the risks and benefits of taking Invirase to you and your unborn baby.
2. You are breastfeeding or plan to breastfeed.

It is not known whether Invirase passes into the breast milk. Your doctor will assess the risks and

benefits of you taking Invirase if you are breastfeeding.

HIV-infected women are recommended not to breast-feed babies in order to avoid transmission of HIV.

3. 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 muscles.
 - a disease of the heart muscles.

Invirase can change the ECG of your heart. This is more common if you are female or elderly. If you experience any changes in your heart rate or palpitations during treatment, you should tell your doctor immediately. Your doctor may want to conduct an ECG to measure your heart rhythm.
4. You have any allergies to any other medicines, foods, preservatives or dyes.
5. You have galactose intolerance, Lapp lactase deficiency or glucose galactose malabsorption (a genetic disorder).

Invirase tablets contain lactose
6. If you have any other health problems, including:
 - kidney or liver disease
 - haemophilia (a condition where you tend to bruise and bleed easily)
 - diabetes (high blood sugar levels)
 - high cholesterol and triglyceride (a type of body fat) levels
 - diarrhoea

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

Taking other medicines

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

Invirase can be taken with a number of other medications used to treat HIV infections.

There are some medications that must not be taken with Invirase. (See: "*Before you start to take it*"). Other medicines that may interfere with Invirase include:

- medicines used to treat fungal

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infections (ketoconazole, itraconazole, fluconazole)

- medicines used to treat epilepsy (phenytoin, phenobarbitone)
- calcium channel blockers used to treat heart conditions (felodipine, nifedipine, verapamil, diltiazem)
- certain heart or blood pressure medicines
- antibiotics (clarithromycin, azithromycin)
- medicines used to treat conditions related to stomach acid (omeprazole, esomeprazole, pantoprazole, lanoprazole)
- St John's wort (*hypericum perforatum*)
- garlic capsules
- medicines used to treat HIV infected patients (indinavir, delavirdine, didanosine)
- medicines used to treat erectile dysfunction (sildenafil, tadalafil)
- medicines used to suppress the immune system (tacrolimus, cyclosporine, rapamycin)
- medicines used to prevent blood clots (warfarin)
- medicines used to treat irregular or fast heart rates (disopyramide, digoxin)
- medicines used to treat night cramps and malaria (quinine)
- medicines to treat tuberculosis and leprosy (dapson)
- strong painkillers used in anaesthesia (fentanyl, alfentanil)
- medicines used to treat anxiety (alprazolam, diazepam, flurazepam)
- medicines used to treat depression (nefazodone, tricyclic antidepressants)
- oestrogen-based oral contraceptives (ethinylestradiol)
- medicines which reduce the activity of the immune system and treat asthma or hayfever (dexamethasone, fluticasone, budesonide)

Please consult your doctor if you are using steroid medicines.

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

need to take different medicines. Your doctor will advise you.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Invirase. Ask your doctor or pharmacist if you are not sure about this list of medicines.

How to take Invirase

How much to take

Follow all directions given to you by your doctor or pharmacist carefully. Invirase should only be taken in combination with ritonavir (a medicine used to treat HIV).

The recommended dosage of Invirase tablets is two 500mg film-coated tablets to be taken twice daily (a total of four tablets per day) and one 100mg capsule of ritonavir to be taken twice daily (a total of two capsules per day).

The recommended dosage of Invirase capsules is five 200mg hard capsules to be taken twice daily (a total of ten capsules per day) and one 100mg capsule of ritonavir to be taken twice daily (a total of two capsules per day). Both medicines should be taken at the same time. Take Invirase exactly as your doctor has prescribed.

How to take it

Film-coated tablets should be swallowed whole with a glass of water. Do not chew the tablets.

When to take it

Invirase should be taken within two hours after a meal. Ritonavir should be taken at the same time as Invirase. Invirase tablets should be taken at the same time every day. This will give you the best effect and will help you remember when to take the medicine every day. If you are not sure when to take Invirase, ask your doctor.

How long to take it

Invirase does not cure your HIV infection but controls it. Therefore, it is important to take Invirase everyday. Continue taking your Invirase tablets until your doctor tells you to stop.

If you forget to take it

Do not try to make up for missed doses by taking an extra dose. This may increase the chance of getting an unwanted side effect. If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to. If you have missed several doses, please inform your doctor and follow the advice given to you.

If you take too much (overdose)

You may need urgent medical attention. Contact your doctor or visit the nearest Accident & Emergency Department immediately (bring along the medication, carton and this leaflet if possible). Do this even if there are no signs of discomfort or poisoning.

While you are using Invirase

Things you must do

If you become pregnant while taking Invirase, tell your doctor immediately. Tell all doctors, dentists and pharmacists who are treating you that you are taking Invirase.

Continue to use safe sexual practices while using Invirase. Invirase has not been shown to reduce the chance of transmitting HIV to your partner. If you are using an oestrogen-based oral contraceptive, you should also be using an additional type of contraception. 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 Invirase tablets are 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 ask you to have regular blood tests to monitor your liver function, blood sugar levels and blood cholesterol levels.

Things you must not do

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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. Do not take any other medicines whether they require prescriptions or not without first consulting with your doctor or a pharmacist.

Things to be careful of

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

Invirase usually does not cause problems with your ability to drive or operate machinery. However, as with many medicines, Invirase may cause dizziness in some people. Thus, make sure you know how you react to Invirase before you drive or operate machinery.

Side effects

Invirase helps most people with HIV infection, but it may have unwanted side effects in a few 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.

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

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
- vomiting
- stomach discomfort/pain/distention/wind
- feeling sick
- constipation
- dizziness or headache
- tiredness, weakness
- skin problems such as itching or rash
- hair loss
- dry mouth/lips
- indigestion, belching after eating
- tingling, numbness, weakness of the arms or legs
- inability to sleep or increased need for sleep
- increased or decreased appetite

- libido disorder
- shortness of breath, difficulty breathing, chest tightness or rapid deep breathing
- muscle spasms
- yellowing of the skin or eyes
- easy bruising or bleeding
- looking pale
- allergic reactions – 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

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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and disposal of Invirase

Storage

Keep out of reach and sight of children.

Do not store above 30°C.

Store the medicine in its bottle until you need to take it in order to protect it from moisture and light.

Disposal

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

Product Description

Availability

Invirase is available in tablet and capsule form.

Invirase tablets and hard-capsules are available in the following pack sizes:

- 200mg - 270 capsules
- 500mg - 120 tablets

What Invirase looks like

The 500mg tablet is light orange to brownish orange in colour and oval in shape. It is engraved with "SQV 500" on one side and "ROCHE" on the other.

Invirase 200mg capsules are light brown and green. Each half of the capsule is marked with the printing "ROCHE" and the code "0245".

Ingredients

Active ingredient

– saquinavir mesylate

- each 500 mg tablet contains 500 mg saquinavir mesylate
- each 200 mg capsule contains 200 mg saquinavir mesylate.

Inactive ingredients

The 500mg film-coated tablets also contain:

- lactose monohydrate 38.5mg
- magnesium stearate
- croscarmellose sodium
- povidone
- microcrystalline cellulose

The tablets are coated with a film-coating which contains:

- hypromellose
- talc
- iron oxide, red
- iron oxide, yellow
- titanium dioxide
- glycerol triacetate

The 200mg capsules contain:

- lactose anhydrous (63.3mg)
- microcrystalline cellulose
- povidone
- sodium starch glycollate
- magnesium stearate
- talc

The capsule shell contains:

- gelatin
- iron oxide black, red and yellow
- indigo carmine
- titanium dioxide
- shellac
- soya leicithin
- polydimethylsiloxane

MAL number:

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Invirase film-coated tablets 500 mg
(MAL07081488A)

Invirase capsules 200 mg
(MAL19970498AR)

Manufacturer

Made for F. Hoffmann-La Roche Ltd,
Basel, Switzerland
by Roche Farma, S. A., Spain.

Product Registration Holder

Roche (M) Sdn. Bhd.
Level 21, The Pinnacle,
Persiaran Lagoon, Bandar Sunway,
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