



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Invirase (*saquinavir*)

An overview of Invirase and why it is authorised in the EU

### What is Invirase and what is it used for?

Invirase is an antiviral medicine used to treat adults infected with the human immunodeficiency virus type 1 (HIV 1), a virus that causes acquired immune deficiency syndrome (AIDS). Invirase should only be used in combination with ritonavir (another antiviral medicine) and other antiviral medicines.

Invirase contains the active substance saquinavir.

### How is Invirase used?

Invirase can only be obtained with a prescription and treatment should be started by a doctor who has experience in the treatment of HIV infection.

Invirase is available as capsules (200 mg) and tablets (500 mg). For patients already taking HIV medicines, the recommended dose of Invirase is 1,000 mg with 100 mg ritonavir twice daily. For patients who are not taking HIV medicines, Invirase is started at 500 mg twice daily with ritonavir 100 mg twice daily for the first 7 days of treatment, given in combination with other HIV medicines. After 7 days, the recommended dose of Invirase is 1,000 mg twice daily with ritonavir 100 mg twice daily in combination with other HIV medicines.

For more information about using Invirase, see the package leaflet or contact a doctor or pharmacist.

### How does Invirase work?

The active substance in Invirase, saquinavir, is a 'protease inhibitor'. It blocks protease, an enzyme involved in the reproduction of HIV. When the enzyme is blocked, the virus does not reproduce normally, slowing down the spread of infection. Ritonavir is another protease inhibitor that is used as a 'booster'. It slows the breakdown of saquinavir, increasing the levels of saquinavir in the blood. This allows effective treatment while avoiding a higher dose of saquinavir. Invirase, taken in combination with other HIV medicines, reduces the viral load (the amount of HIV in the blood) and keeps it at a low level. Invirase does not cure HIV infection or AIDS, but it may hold off the damage to the immune system and the development of infections and diseases associated with AIDS.



## **What benefits of Invirase have been shown in studies?**

Invirase was found effective in the treatment of HIV infection in six main studies involving a total of 1,576 patients.

In the first four studies, Invirase in combination with other HIV medicines, but without ritonavir, reduced the viral load and improved the immune system.

Two further studies involving 656 patients compared Invirase with indinavir or lopinavir (other HIV medicines). The medicines were given in combination with ritonavir and two other HIV medicines. These studies measured the viral load after 48 weeks. Invirase in combination with ritonavir was as effective as indinavir but more effective than lopinavir in reducing the viral load to less than 50 copies/ml.

## **What are the risks associated with Invirase?**

The most common side effects when taking Invirase in combination with ritonavir (which may affect more than 1 patient in 10) are diarrhoea, nausea (feeling sick), increased levels of liver enzymes, cholesterol and triglycerides (a type of fat) in the blood, and decreased levels of platelets in the blood (components that help blood to clot). For the full list of side effects of Invirase, see the package leaflet.

Invirase must not be used in patients who have severe problems with their liver, QT prolongation (an alteration of the electrical activity of the heart), abnormal levels of electrolytes in the blood (especially low potassium levels), bradycardia (slow heart rate) or heart failure (when the heart does not work as well as it should). It must not be used in patients who have had arrhythmia (unstable heartbeat). It must also not be used in patients who are taking any of the following medicines which could cause harmful side effects if taken with Invirase:

- medicines that could cause QT prolongation or PR prolongation (another type of heart activity alteration);
- midazolam taken by mouth, triazolam (used to relieve anxiety or difficulty sleeping);
- simvastatin, lovastatin (used to lower cholesterol);
- ergot alkaloids, such as ergotamine, dihydroergotamine, ergonovine and methylergonovine (used to treat migraine headache);
- rifampicin (used to treat tuberculosis);
- lurasidone, quetiapine (used to treat psychiatric illness such as schizophrenia).

For the full list of restrictions, see the package leaflet.

## **Why is Invirase authorised in the EU?**

The European Medicines Agency decided that Invirase's benefits are greater than its risks and it can be authorised for use in the EU.

## **What measures are being taken to ensure the safe and effective use of Invirase?**

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Invirase have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Invirase are continuously monitored. Side effects reported with Invirase are carefully evaluated and any necessary action taken to protect patients.

### **Other information about Invirase**

Invirase received a marketing authorisation valid throughout the EU on 4 October 1996.

Further information on Invirase can be found on the Agency's website: [ema.europa.eu/Find/medicine/Human\\_medicines/European\\_public\\_assessment\\_reports](http://ema.europa.eu/Find/medicine/Human_medicines/European_public_assessment_reports).

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