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EPAR summary for the public

Crixivan

indinavir

This is a summary of the European public assessment report (EPAR) for Crixivan. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Crixivan.

For practical information about using Crixivan, patients should read the package leaflet or contact their doctor or pharmacist.

What is Crixivan and what is it used for?

Crixivan is an antiviral medicine for treating adults infected with human immunodeficiency virus type 1 (HIV 1), a virus that causes acquired immune deficiency syndrome (AIDS).

Crixivan is used in combination with other antiviral medicines and contains the active substance indinavir.

How is Crixivan used?

Crixivan is available as capsules (200 and 400 mg) and is taken by mouth one hour before or two hours after a meal with water or a light low-fat meal. The standard dose is 800 mg every eight hours, but Crixivan can also be taken at a dose of 400 mg twice a day if each dose is taken with 100 mg ritonavir (another antiviral medicine). To avoid the risk of developing kidney stones, patients should drink plenty of liquids (at least 1.5 litres every day for adults).

Crixivan should only be prescribed by doctors with experience in treating HIV and can only be obtained by prescription.

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How does Crixivan work?

The active substance in Crixivan, indinavir, is a protease inhibitor. It blocks an enzyme called protease, which is involved in the reproduction of HIV. By blocking this enzyme, indinavir stops the virus from reproducing normally and thereby slows down the spread of infection.

Crixivan does not cure HIV infection or AIDS, but it can hold off damage to the immune system and the development of infections and diseases associated with AIDS.

Ritonavir, another protease inhibitor, is sometimes used with Crixivan as a 'booster'. It slows down the rate at which indinavir is broken down, helping to increase levels of indinavir in the blood.

What benefits of Crixivan have been shown in studies?

Studies have shown that Crixivan in combination with other antiviral medicines is effective at reducing the level of HIV in the blood (viral load). In one study, 90% of those taking Crixivan in combination with zidovudine and lamivudine had viral loads below 500 copies/ml after 24 weeks of treatment, compared with 43% of those taking Crixivan alone and none (0%) of those taking zidovudine and lamivudine without Crixivan.

What are the risks associated with Crixivan?

The most common side effects with Crixivan (seen in more than 1 patient in 10) are increases in size of red blood cells, decreases in neutrophils (a type of white blood cell), headache, dizziness, nausea (feeling sick), vomiting, diarrhoea, heartburn, instances of high blood bilirubin levels that do not cause any symptoms, increased levels of liver enzymes (alanine and aspartate transaminases), rash, dry skin, blood in the urine, protein in the urine, crystals in the urine, weakness or tiredness, an altered sense of taste and abdominal pain (stomach ache). For the full list of side effects reported with Crixivan, see the package leaflet.

Crixivan must not be taken with certain other medicines because of the possibility of harmful interactions. For the full list of restrictions, see the package leaflet.

Why is Crixivan been approved?

The CHMP decided that Crixivan's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Crixivan?

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

Other information about Crixivan

The European Commission granted a marketing authorisation valid throughout the European Union for Crixivan on 4 October 1996.

The full EPAR for Crixivan can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Crixivan, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2016.