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EPAR summary for the public

Stocrin

efavirenz

This is a summary of the European public assessment report (EPAR) for Stocrin. 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 Stocrin.

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

What is Stocrin and what is it used for?

Stocrin is an antiviral medicine that is used together with other antiviral medicines to treat patients aged three years or older infected with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS).

How is Stocrin used?

Stocrin can only be obtained with a prescription and treatment should be started by a doctor who has experience in the management of HIV infection. It is available as capsules, tablets and oral solution and must be given in combination with other antiviral medicines. It is recommended that Stocrin be taken on an empty stomach and without food, preferably at bedtime.

The recommended dose of Stocrin for adults is 600 mg once a day. In patients aged 3 to 17 years, the dose depends on body weight. For patients who are unable to swallow the capsules or tablets, Stocrin can be given using the oral solution. The dose of Stocrin may need to be adjusted in patients taking certain other medicines at the same time.

For full details, see the summary of product characteristics (also part of the EPAR).

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How does Stocrin work?

The active substance in Stocrin, efavirenz, is a non-nucleoside reverse transcriptase inhibitor (NNRTI). It blocks the activity of reverse transcriptase, an enzyme produced by HIV that allows it to reproduce itself in the cells it has infected. By blocking this enzyme, Stocrin, taken in combination with other antiviral medicines, reduces the amount of HIV in the blood and keeps it at a low level. Stocrin does not cure HIV infection or AIDS, but it can hold off damage to the immune system and avoid the development of infections and diseases associated with AIDS.

What benefits of Stocrin have been shown in studies?

Stocrin has shown benefit in controlling HIV infection in three main studies involving over 1,100 adults. In all of the studies, the main measure of effectiveness was the number of patients with undetectable levels of HIV-1 in their blood (viral loads) after 24 or 48 weeks of treatment:

- in the first study, Stocrin in combination with lamivudine and zidovudine or with indinavir (other antiviral medicines) was compared with the combination of indinavir, lamivudine and zidovudine. 67% of the adults treated with Stocrin in combination with zidovudine and lamivudine had viral loads below 400 copies/ml after 48 weeks, compared with 54% of the patients treated with Stocrin and indinavir, and 45% of the patients treated with indinavir, lamivudine and zidovudine;
- the second study compared Stocrin in combination with nelfinavir and two other antiviral medicines with the same combination without Stocrin. The Stocrin combination was more effective than the combination without Stocrin: 70% and 30% of the patients, respectively, had viral loads below 500 copies/ml after 48 weeks;
- the third study compared adding Stocrin or placebo (a dummy treatment) to a combination of antiviral medicines that included indinavir and two other antiviral medicines, in patients who had already been receiving treatment for HIV infection. More patients receiving Stocrin had viral loads below 400 copies/ml than those taking placebo after 24 weeks

Similar results were seen in a study in 57 children aged between 3 and 16 years, given Stocrin in combination with nelfinavir and other antiviral medicines.

What are the risks associated with Stocrin?

The most common side effect with Stocrin (seen in more than 1 patient in 10) is rash. Stocrin is also commonly associated with dizziness, headache, nausea (feeling sick) and tiredness. Taking Stocrin with food may lead to an increase in the frequency of side effects. For the full list of side effects reported with Stocrin, see the package leaflet.

Stocrin must not be used in patients with severe liver disease. Stocrin can affect the electrical activity of the heart and so must also not be used in patients with heart problems such as changes in heart rhythm and activity, slow heart rate or heart failure or other conditions that can affect the heart's electrical activity, or who have close relatives that have died suddenly from a heart condition or were born with heart problems. Similarly, it must not be used in patients with altered levels of salts (electrolytes) such as potassium or magnesium in their blood.

Stocrin must be avoided if patients are taking certain medicines because it can increase their side effects or reduce their effectiveness, or because the combination may increase effects on the heart. See the package leaflet for further details.

Why is Stocrin approved?

The European Medicines Agency decided that Stocrin's benefits are greater than its risks in antiviral combination treatment of HIV-infected adults, adolescents, and children three years of age and older and recommended that it be approved for use in the EU. The Agency noted that Stocrin has not been studied adequately in patients with advanced disease (CD4 cell counts below 50 cells/mm^3) or after treatment with protease inhibitors (another type of antiviral medicine) that was not working. It also noted that there is little information on the benefits of treatment that includes a protease inhibitor in patients who have been treated with Stocrin in the past but which stopped working, although there is no evidence to suggest that protease inhibitors may not work in these patients.

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

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

Other information about Stocrin

The European Commission granted a marketing authorisation valid throughout the European Union for Stocrin on 28 May 1999.

The full EPAR for Stocrin 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 Stocrin, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 12-2017.