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EPAR summary for the public

Sustiva

efavirenz

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

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

What is Sustiva and what is it used for?

Sustiva is an antiviral medicine that is used together with other antiviral medicines to treat patients aged 3 months or older and weighing at least 3.5 kg, who are infected with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS).

How is Sustiva used?

Sustiva 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 and tablets and must be given in combination with other antiviral medicines. It is recommended that Sustiva be taken on an empty stomach and without food, preferably at bedtime.

The recommended dose of Sustiva for adults is 600 mg once a day. In patients aged 3 months to 17 years, the dose depends on body weight. For patients who cannot swallow, the capsule contents can be mixed with a small amount of food (one or two teaspoons). The dose of Sustiva 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 Sustiva work?

The active substance in Sustiva, 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, Sustiva, taken in combination with other antiviral medicines, reduces the amount of HIV in the blood and keeps it at a low level. Sustiva 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 Sustiva have been seen in studies?

Sustiva 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, Sustiva 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 Sustiva in combination with zidovudine and lamivudine had viral loads below 400 copies/ml after 48 weeks, compared with 54% of the patients treated with Sustiva and indinavir, and 45% of the patients treated with indinavir, lamivudine and zidovudine;
- the second study compared Sustiva in combination with nelfinavir and two other antiviral medicines with the same combination without Sustiva. The Sustiva combination was more effective than the combination without Sustiva: 70% and 30% of the patients, respectively, had viral loads below 500 copies/ml after 48 weeks;
- the third study compared adding Sustiva 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 Sustiva had viral loads below 400 copies/ml than those taking placebo after 24 weeks

Similar results have been seen in studies involving 182 patients (of whom 177 were children aged between 3 months and 18 years) in combination with nelfinavir and other antiviral medicines.

What are the risks associated with Sustiva?

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

Sustiva must not be used in patients with severe liver disease. Sustiva 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.

Sustiva 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 Sustiva approved?

The European Medicines Agency decided that Sustiva's benefits are greater than its risks in antiviral combination treatment of HIV-infected adults, adolescents and children three months of age and older and recommended that it be approved for use in the EU. The Agency noted that Sustiva 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 include a protease inhibitor in patients who have been treated with Sustiva 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 Sustiva?

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

Other information about Sustiva

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

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

This summary was last updated in 12-2017.