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EPAR summary for the public

Viramune

nevirapine

This is a summary of the European public assessment report (EPAR) for Viramune. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Viramune.

What is Viramune?

Viramune is a medicine that contains the active substance nevirapine. It is available as immediate-release (200 mg) and prolonged-release tablets (50, 100 and 400 mg) and as an oral suspension (50 mg/5 ml).

Immediate-release tablets release the active substance immediately, and prolonged-release tablets release it slowly over a few hours which allows it to be given less frequently.

What is Viramune used for?

Viramune is an antiviral medicine. It is used in combination with other antiviral medicines to treat patients infected with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS).

The medicine can only be obtained with a prescription.

How is Viramune used?

Treatment with Viramune should be given by a doctor who has experience in the treatment of HIV infection.

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Viramune is never taken on its own. It must be taken with at least two other antiviral medicines. Because the medicine can cause serious rash, treatment should be started at low doses.

For adults, treatment should start with 200 mg immediate-release tablets or oral suspension once a day for two weeks. The dose should then be increased to the standard dose of 200 mg twice a day using immediate release tablets or oral suspension or to the standard dose of 400mg once a day using the prolonged-release tablets are prescribed.

For children and adolescents, the starting dose is 150 mg per square metre of body surface area (calculated using the child's height and weight) or 4 mg/kg once a day for two weeks with Viramune oral suspension, after which the dose should be increased to a maintenance dose (calculated using the patient's body surface area or weight).

The dose should not be increased to the maintenance dose until any rash has cleared. If the patient cannot switch to the full dose within four weeks of starting Viramune, alternative treatments should be sought.

The prolonged-released tablets are not suitable for the initial two week phase for patients starting on Viramune and should not be used until any rash has cleared. The prolonged-release tablets have not been tested in children under 3 years of age. The prolonged-release tablets must not be broken or chewed.

For more information, see the package leaflet.

How does Viramune work?

The active substance in Viramune, nevirapine, is a non-nucleoside reverse transcriptase inhibitor (NNRTI). It blocks the activity of reverse transcriptase, an enzyme produced by HIV-1 that allows it to infect cells in the body and make more viruses. By blocking this enzyme, Viramune, taken in combination with other antiviral medicines, reduces the amount of HIV-1 in the blood and keeps it at a low level. Viramune does not cure HIV-1 infection or AIDS, but it may delay the damage to the immune system and the development of infections and diseases associated with AIDS.

How has Viramune been studied?

Viramune immediate-release has been studied in five studies involving a total of 1,956 adults. The studies compared Viramune, taken in combination with zidovudine and didanosine (other antiviral medicines), with other antiviral medicines. Viramune, taken alone or in combination with one or two other antiviral medicines, has also been studied in two studies including 478 children. The main measures of effectiveness were the change in the level of HIV in the blood (viral load) and in the number of CD4 T-cells in the blood (CD4 cell count), and the number of patients whose disease got worse or who died. CD4 T-cells are white blood cells that are important in helping to fight infections but which are killed by HIV.

To support the use of the prolonged-release tablets, the company conducted studies to show that the immediate- and prolonged-release tablets both had adequate drug levels, and the same effect on the viral load in the body.Studies were also done to show successful switching from immediate-release tablets, twice daily to prolonged-release tablets, once daily.

What benefit has Viramune shown during the studies?

Viramune, taken in combination with two other antiviral medicines, was more effective than combinations of two medicines. In 398 treatment-experienced adults (who had taken treatment for HIV infection before), Viramune in combination with zidovudine and lamivudine led to a 38% reduction in viral load after 48 weeks, compared with a 28% rise in those taking zidovudine and lamivudine without Viramune. In 151 treatment-naïve patients (who had not taken treatment for HIV infection before), viral load fell by 99% in the three-medicine group, compared with 96% in the two-medicine group after 40 to 52 weeks. Adults taking three medicines also had greater rises in CD4 cell counts, and a lower risk of their disease getting worse or of dying. Similar results were seen in HIV-1-infected children.

The additional studies showed that the prolonged-release tablets were as effective as the immediate-release tablets in HIV-infected patients. They also showed that patients can be safely switched from immediate- to prolonged-release tablets.

What is the risk associated with Viramune?

The most common side effects with Viramune (seen in between 1 and 10 patients in 100) are rash, headache, nausea (feeling sick), fatigue, abdominal pain, diarrhoea, fever, hepatitis (inflammation of the liver) and signs of liver problems in the blood. Viramune has also been associated with serious side effects, including Stevens-Johnson syndrome and toxic epidermal necrolysis (life-threatening allergic reactions affecting the skin and mucous membranes), serious hepatitis and liver failure, and serious allergic reactions. Patients should be monitored closely for signs of these side effects during the first 18 weeks of treatment, and blood tests for liver problems should be carried out regularly throughout treatment. For the full list of all side effects reported with Viramune, see the package leaflet.

Viramune must not be used in people who are hypersensitive (allergic) to nevirapine or any of the other ingredients. It must not be used in patients who have severe problems with their liver or signs of liver problems in the blood, or who are taking St John's wort (a herbal preparation used to treat depression). Treatment with Viramune must not be started again in patients who have had to stop taking the medicine in the past because of rash, allergic reactions or hepatitis, or who had signs of liver problems while they were taking Viramune that returned when the medicine was started again.

Why has Viramune been approved?

The Committee for Medicinal Products for Human Use (CHMP) decided that Viramune's benefits are greater than its risks in combination with other antiviral medicinal products for the treatment of HIV-1 infected adults, adolescents, and children of any age.

The Committee noted that most of the experience with Viramune was in combination with nucleoside reverse transcriptase inhibitors (NRTIs, a type of antiviral medicine) and that there was insufficient evidence on the use of combination treatment including a protease inhibitor (another type of antiviral medicine) after Viramune treatment. The Committee recommended that Viramune be given marketing authorisation.

Viramune was originally authorised under 'exceptional circumstances', because, for scientific reasons, limited information was available at the time of the approval. As the company had supplied the additional information requested, the 'exceptional circumstances' ended on 11 July 2002.

Other information about Viramune

The European Commission granted a marketing authorisation valid throughout the European Union for Viramune on 5 February 1998.

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

This summary was last updated in 09- 2011.