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Viramune (*nevirapine*)

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

What is Viramune and what is it used for?

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

Viramune contains the active substance nevirapine.

How is Viramune used?

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

Viramune is available as tablets and as a liquid to be taken by mouth. Because the medicine can cause serious rash, treatment should be started at low doses.

For more information about using Viramune, see the package leaflet or contact your doctor or pharmacist.

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 reproduce itself in the cells it has infected. 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 can hold off damage to the immune system and avoid the development of infections and diseases associated with AIDS.

What benefit of Viramune have been shown in studies?

Viramune has been studied in five studies involving a total of 1,956 adults. The main measures of effectiveness were the reduction in the amount of HIV in the blood (viral load), the rise in 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 involved in fighting infections but which are reduced by HIV.

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Viramune, taken in combination with two other antiviral medicines, was more effective than combinations of two medicines. In 398 adults who had taken treatment for HIV infection before, Viramune in combination with the antiviral medicines zidovudine and lamivudine led to a 38% fall in viral load after 48 weeks, compared with a 28% rise in those taking zidovudine and lamivudine without Viramune. In 151 patients who had not taken treatment for HIV-1 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. In adults taking three medicines the rise in CD4 cell counts was greater, and fewer patients got worse or died.

Two studies involved 478 children with HIV-1 taking Viramune alone or in combination with one or two other antiviral medicines. The results in children were similar to those in adults.

What are the risks associated with Viramune?

For the full list of side effects and restrictions with Viramune, see the package leaflet.

The most common side effects with Viramune (which may affect up to 1 and 10 people) include rash, allergic reactions, hepatitis (inflammation of the liver), blood tests showing liver changes, nausea (feeling sick), vomiting, diarrhoea, abdominal (belly) pain, tiredness, fever, headache and muscle pain.

The most serious side effects are 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 affecting several parts of the body.

The first 18 weeks of treatment are a critical period which requires close monitoring of patients for possible severe and life-threatening skin reactions and serious liver failure. Patients developing signs or symptoms of hepatitis, severe skin reaction or hypersensitivity reactions must stop taking Viramune and immediately consult a healthcare professional.

Viramune must not be used in patients who have severe problems with their liver or have signs of liver problems, or who are taking St John’s wort (a herbal remedy 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 is Viramune authorised in the EU?

The European Medicines Agency decided that Viramune’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 Viramune?

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

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

Other information about Viramune

Viramune received a marketing authorisation valid throughout the EU on 5 February 1998.

Further information on Viramune can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/viramune

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