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EPAR summary for the public

Viracept

nelfinavir

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

What is Viracept?

Viracept is a medicine containing the active substance nelfinavir. It is available as an oral powder (50 mg per gram) and as tablets (250 mg).

What is Viracept used for?

Viracept is an antiviral medicine. It is used in combination with other antiviral medicines to treat adults, adolescents and children over three years of age who are infected with human immunodeficiency virus (HIV-1), the virus that causes acquired immune deficiency syndrome (AIDS).

Doctors should only prescribe Viracept to patients who have already taken medicines in the same class as Viracept (protease inhibitors) once they have looked at the antiviral medicines the patient has taken before and the likelihood that the virus will respond to the medicine.

The medicine can only be obtained with a prescription.

How is Viracept used?

Treatment with Viracept should be initiated by a doctor who has experience in the treatment of HIV infection. For patients aged over 13 years, the recommended dose of Viracept is 1,250 mg twice a day or 750 mg three times a day, taken with food. The dose for children aged three to 13 years depends on their body weight. For patients unable to swallow the tablets, Viracept tablets may be dispersed in water or the oral powder may be used instead. Viracept should be used with caution in patients who have problems with their liver or kidneys. For more information, see the package leaflet.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

How does Viracept work?

The active substance in Viracept, nelfinavir, is a protease inhibitor. It blocks an enzyme called protease that is involved in the reproduction of HIV. When the enzyme is blocked, the virus does not reproduce normally, slowing down the spread of infection. Viracept, taken in combination with other antiviral medicines, reduces the amount of HIV in the blood and keeps it at a low level. Viracept does not cure HIV 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 Viracept been studied?

Viracept has been studied in combination with other antiviral medicines in two main studies involving 605 patients aged 13 years or more, who were infected with HIV. In the first study, Viracept in combination with stavudine (another antiviral medicine) was compared with stavudine alone in 308 patients who had not taken stavudine or a protease inhibitor in the past. In the second study, Viracept, in combination with zidovudine and lamivudine (other antiviral medicines) was compared with the combination of zidovudine and lamivudine in 297 treatment-naïve patients (who had not taken any antiviral medicines to treat HIV infection before). The main measures of effectiveness were the change in the levels of HIV in the blood (viral load) and the change in the number of CD4 T-cells in the blood (CD4 cell count). CD4 T-cells are white blood cells that are important in helping to fight infections, but which are killed by HIV.

Three studies have compared the effectiveness of dosing Viracept twice and three times a day, in combination with stavudine and lamivudine in 635 patients. Most of these patients had not taken protease inhibitors in the past. Viracept has also been studied in 37 children.

What benefit has Viracept shown during the studies?

Viracept, in combination with other antiviral medicines, was more effective than the comparator medicines in both main studies. After 24 weeks, Viracept brought about greater reductions in viral load and increases in CD4 cell counts than the comparator medicines. There were no differences between the two doses of Viracept. In the second study, viral load had fallen by more than 99% in the patients taking the higher dose of Viracept, compared with 95% in those taking the comparator medicines. CD4 cell counts increased by 150 and 95 cells/mm3, respectively.

Viracept brought about similar reductions in viral load whether it was taken twice or three times a day. The study in children showed that the medicine produced similar levels of the active substance in the blood in children and adults, with similar side effects and effectiveness.

What is the risk associated with Viracept?

The most common side effect with Viracept (seen in more than 1 patient in 10) is diarrhoea. For the full list of all side effects seen with Viracept, see the package leaflet.

Viracept must not be used in people who are hypersensitive (allergic) to nelfinavir or any of the other ingredients. Viracept should not be used in patients who are taking any of the following medicines:

- rifampicin (used to treat tuberculosis);
- St John's wort (a herbal preparation used to treat depression);
- omeprazole (used to reduce stomach acid levels);

- medicines that are broken down in the same way as Viracept and are harmful at high levels in the blood. See the package leaflet for the full list of these medicines.

Doctors should consider using alternatives to medicines that speed up the breakdown of Viracept, such as phenobarbital and carbamazepine (used to treat epilepsy), in patients taking Viracept. Caution is needed when Viracept is taken at the same time as other medicines. See the package leaflet for full details.

Why has Viracept been approved?

The CHMP decided that Viracept's benefits are greater than its risks in antiviral combination treatment of HIV-1 infected adults, adolescents and children of three years of age and older. The Committee and recommended that it be given marketing authorisation.

Other information about Viracept

The European Commission granted a marketing authorisation valid throughout the European Union for Viracept on 22 January 1998.

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

This summary was last updated in 08-2011.