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Viread (*tenofovir disoproxil*)

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

What is Viread and what is it used for?

Viread is a medicine used to treat patients aged 2 years and above infected with human immunodeficiency virus type 1 (HIV 1), a virus that causes acquired immune deficiency syndrome (AIDS). Viread is used in combination with other HIV medicines. In children and adolescents it is only used in patients who cannot be treated with other first-line nucleotide reverse transcriptase inhibitors (NRTI). For patients who have taken medicines to treat HIV infection before, doctors should only prescribe Viread once they have looked at the antiviral medicines the patient has taken before or the likelihood that the virus will respond to antiviral medicines.

Viread is also used to treat chronic (long-term) hepatitis B virus infection in adults and children aged 2 years and above with liver damage whose liver is still working properly (compensated liver disease). In adults, it can also be used for those patients with liver damage whose liver is not working properly (decompensated liver disease) and those patients who do not respond to treatment with lamivudine (another medicine for hepatitis B infection).

Viread contains the active substance tenofovir disoproxil.

How is Viread used?

Viread can only be obtained with a prescription and treatment should be started by a doctor who has experience in the treatment of HIV infection or chronic hepatitis B. Viread, available as tablets and as granules, is taken once a day with food. The dose may need to be reduced or the medicine given less often in patients who have moderately or severely reduced kidney function. For more information about using Viread, see the package leaflet or contact your doctor or pharmacist.

How does Viread work?

The active substance in Viread, tenofovir disoproxil, is a 'prodrug' that is converted into tenofovir in the body.

Tenofovir is a nucleotide reverse transcriptase inhibitor (NRTI). In HIV infection, it blocks the activity of reverse transcriptase, an enzyme produced by HIV that allows it to infect cells and make more viruses. Viread, taken in combination with other antiviral medicines, reduces the amount of HIV in the blood

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and keeps it at a low level. Viread 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.

Tenofovir also interferes with the action of an enzyme produced by the hepatitis B virus called DNA polymerase, which is involved in the formation of viral DNA. Viread stops the virus making DNA and prevents it from multiplying and spreading.

What benefits of Viread have been shown in studies?

HIV

For the treatment of HIV, Viread was more effective than placebo (a dummy treatment) when added to existing treatment. Two studies involving 741 HIV-infected adults showed that Viread resulted in a fall in the levels of HIV in the blood (viral load) of around 75% after 4 and after 24 weeks, compared with a small rise or fall in viral load of around 5% in the patients taking placebo. In a third study Viread was as effective as another medicine stavudine, when added to lamivudine and efavirenz. Similar numbers of patients in the Viread and stavudine groups had viral loads below 400 copies/ml after 48 weeks.

A study carried out in 87 adolescents (12 to 18 years of age) investigated the effects of adding Viread to existing treatment. Although it showed no benefit of adding Viread to existing treatment compared with adding placebo, Viread produced similar levels of the active substance in the body compared to adults, and it was judged that the results were influenced by the type of patients included in the Viread group.

A study in 97 children (aged 2 to 12 years) treated with stavudine or zidovudine, compared the effects of switching their treatment to Viread with continuing previous treatment. It showed that the majority of those who switched treatment from stavudine or zidovudine maintained their low HIV blood levels on Viread (83% of children in the Viread group and 92% of those on stavudine or zidovudine had viral loads below 400 copies/ml after 48 weeks).

Hepatitis B

For the treatment of hepatitis B, two studies involving 641 adult patients compared Viread with another medicine, adefovir dipivoxil. One of these studies involved patients with ‘HBeAg-negative’ hepatitis B, a type that is more difficult to treat, while the other involved the more common ‘HBeAg-positive’ hepatitis B. After 48 weeks, 71% of the HBeAg-negative and 67% of HBeAg-positive patients taking Viread had a complete response to treatment, compared with 49% and 12%, respectively, of the patients taking adefovir dipivoxil.

In a third study involving 112 adults whose liver had stopped working properly (decompensated liver disease) Viread was compared with entecavir and a combination treatment of Viread and emtricitabine. Overall, 70% of patients taking Viread or entecavir had a viral load below 400 copies/ml. The figure for the combination treatment of Viread and emtricitabine was 88%. A fourth study, involving 280 adults who had not responded to treatment with lamivudine, compared Viread alone with a combination treatment of Viread and emtricitabine. 89% of patients taking Viread had a viral load below 400 copies/ml after 96 weeks of treatment, compared with 86% of patients taking the combination treatment of Viread and emtricitabine.

A study in 106 adolescents with either HBeAg-negative or HBeAg-positive hepatitis B compared Viread with placebo and found that in 88% of patients taking Viread the viral load reduced to below 400 copies/ml after 72 weeks compared with 0% of those taking placebo. In a study in 89 children aged between 2 and 12 years the results were similar: 77% of patients on Viread had a viral load reduced to below 400 copies/ml after 48 weeks compared with 7% of patients on placebo.

What are the risks associated with Viread?

The most common side effects with Viread (seen in more than 1 patient in 10) are nausea (feeling sick), vomiting, diarrhoea, dizziness, hypophosphataemia (low levels of phosphate in the blood), rash and asthenia (weakness). Rare cases of severe kidney problems have also been seen in patients treated with Viread. Moreover, Viread may cause a reduction in bone density. For the full list of side effects and restrictions with Viread, see the package leaflet.

Why is Viread authorised in the EU?

The European Medicines Agency decided that Viread's benefits are greater than its risks and it can be authorised for use in the EU.

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

The company that makes Viread will ensure that all doctors who are expected to prescribe or use Viread in children are provided with educational materials containing important safety information, particularly on the risks and precautions relating to kidney function and the bones.

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

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

Other information about Viread:

Viread received a marketing authorisation valid throughout the EU on 5 February 2002.

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

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