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Emtricitabine/Tenofovir disoproxil Zentiva (*emtricitabine / tenofovir disoproxil*)

An overview of Emtricitabine/Tenofovir disoproxil Zentiva and why it is authorised in the EU

What is Emtricitabine/Tenofovir disoproxil Zentiva and what is it used for?

Emtricitabine/Tenofovir disoproxil Zentiva is used in combination with at least one other HIV medicine to treat adults infected with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS). In addition it may be used from the age of 12 years in adolescents with HIV that is resistant to first-line treatments or who cannot take them because of side effects.

Emtricitabine/Tenofovir disoproxil Zentiva is also used to help prevent sexually transmitted HIV-1 infection in adults and adolescents who are at high risk of being infected (pre-exposure prophylaxis or PrEP). It should be used in combination with safer sex practices, such as use of condoms.

Emtricitabine/Tenofovir disoproxil Zentiva contains two active substances, emtricitabine (200 mg) and tenofovir disoproxil (245 mg). It is a 'generic medicine'. This means that Emtricitabine/Tenofovir disoproxil Zentiva contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Truvada. For more information on generic medicines, see the question-and-answer document here.

How is Emtricitabine/Tenofovir disoproxil Zentiva used?

Emtricitabine/Tenofovir disoproxil Zentiva can only be obtained with a prescription and treatment should be started by a doctor who is experienced in managing HIV infection.

Emtricitabine/Tenofovir disoproxil Zentiva is available as tablets. The recommended dose for treating or preventing HIV-1 infection is one tablet once a day, preferably taken with food. If patients with HIV-1 infection need to stop taking emtricitabine or tenofovir, or need to take different doses, they will need to take medicines containing emtricitabine or tenofovir disoproxil separately.

For more information about using Emtricitabine/Tenofovir disoproxil Zentiva, see the package leaflet or contact your doctor or pharmacist.

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Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

How does Emtricitabine/Tenofovir disoproxil Zentiva work?

Emtricitabine/Tenofovir disoproxil Zentiva contains two active substances: emtricitabine, which is a nucleoside reverse transcriptase inhibitor; and tenofovir disoproxil, which is a 'prodrug' of tenofovir. This means that it is converted into tenofovir in the body. Tenofovir is a nucleotide reverse transcriptase inhibitor. Both emtricitabine and tenofovir work in similar ways by blocking the activity of reverse transcriptase, an enzyme produced by HIV that allows it to infect cells and make more viruses.

For the treatment of HIV-1 infection, Emtricitabine/Tenofovir disoproxil Zentiva, taken in combination with at least one other HIV medicine, reduces the amount of HIV in the blood and keeps it at a low level. Emtricitabine/Tenofovir disoproxil Zentiva does not cure HIV infection or AIDS, but it may hold off damage to the immune system and the development of infections and diseases associated with AIDS.

For pre-exposure prophylaxis of HIV-1 infection, it is expected that Emtricitabine/Tenofovir disoproxil Zentiva in the blood will stop the virus from multiplying and spreading from the site of infection in case the individual is exposed to the virus.

Both active substances have been authorised in the EU since the early 2000s: emtricitabine was authorised as Emtriva in 2003, and tenofovir disoproxil was authorised as Viread in 2002.

How has Emtricitabine/Tenofovir disoproxil Zentiva been studied?

Studies on the benefits and risks of the active substances in the authorised uses have already been carried out with the reference medicine, Truvada, and do not need to be repeated for Emtricitabine/Tenofovir disoproxil Zentiva.

As for every medicine, the company provided studies on the quality of Emtricitabine/Tenofovir disoproxil Zentiva. The company also carried out a study that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the benefits and risks of Emtricitabine/Tenofovir disoproxil Zentiva?

Because Emtricitabine/Tenofovir disoproxil Zentiva is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Emtricitabine/Tenofovir disoproxil Zentiva authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Emtricitabine/Tenofovir disoproxil Zentiva has been shown to have comparable quality and to be bioequivalent to Truvada. Therefore, the Agency's view was that, as for Truvada, the benefits of Emtricitabine/Tenofovir disoproxil Zentiva outweigh the identified risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Emtricitabine/Tenofovir disoproxil Zentiva?

The company that markets Emtricitabine/Tenofovir disoproxil Zentiva will provide an information pack to doctors, which covers the potential harmful effects of Emtricitabine/Tenofovir disoproxil Zentiva on kidney function, and information about use in adults for pre-exposure prophylaxis. Healthcare

professionals will also receive a brochure and reminder card to hand out to individuals receiving the medicine for pre-exposure prophylaxis.

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

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

Other information about Emtricitabine/Tenofovir disoproxil Zentiva

Emtricitabine/Tenofovir disoproxil Zentiva received a marketing authorisation valid throughout the EU on 9 November 2016.

Further information on Emtricitabine/Tenofovir disoproxil Zentiva can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/emtricitabinetenofovir-disoproxil-zentiva. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 09-2019.