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EPAR summary for the public

Tenofovir disoproxil Zentiva

tenofovir disoproxil

This is a summary of the European public assessment report (EPAR) for Tenofovir disoproxil Zentiva. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Tenofovir disoproxil Zentiva.

For practical information about using Tenofovir disoproxil Zentiva, patients should read the package leaflet or contact their doctor or pharmacist.

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

Tenofovir disoproxil Zentiva is an antiviral medicine used to treat patients aged 12 years and above infected with human immunodeficiency virus type 1 (HIV 1), a virus that causes acquired immune deficiency syndrome (AIDS). Tenofovir disoproxil Zentiva is used in combination with other HIV medicines. In adolescents (from 12 to 18 years of age) its use is only for those 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 Tenofovir disoproxil Zentiva once they have looked at the antiviral medicines the patient has taken before or the likelihood of the virus's response to antiviral medicines.

Tenofovir disoproxil Zentiva is also used to treat chronic (long-term) hepatitis B virus infection in adults and adolescents aged 12 years and above with liver damage whose liver is still able to work (compensated liver disease). In adults, it can also be used for those patients with liver damage whose liver does not work properly (decompensated liver disease) and those patients who do not respond to treatment with lamivudine (another medicine for hepatitis B).

Tenofovir disoproxil Zentiva contains the active substance tenofovir disoproxil. It is a 'generic medicine'. This means that Tenofovir disoproxil Zentiva is similar to a 'reference medicine' already

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authorised in the European Union (EU) called Viread. For more information on generic medicines, see the question-and-answer document here.

How is Tenofovir disoproxil Zentiva used?

Tenofovir disoproxil Zentiva 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.

Tenofovir disoproxil Zentiva is available as tablets (245 mg) to be taken by mouth. It 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 on how the medicine is taken including doses for adults and adolescents, see the summary of product characteristics (also part of the EPAR).

How does Tenofovir disoproxil Zentiva work?

The active substance in Tenofovir disoproxil Zentiva, 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. Tenofovir disoproxil Zentiva, taken in combination with other antiviral medicines, reduces the amount of HIV in the blood and keeps it at a low level. Tenofovir disoproxil Zentiva does not cure HIV infection or AIDS, but it can hold off damage to the immune system and avoid 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. Tenofovir disoproxil Zentiva stops the virus making DNA and prevents it from multiplying and spreading.

How has Tenofovir disoproxil Zentiva been studied?

Because Tenofovir disoproxil Zentiva is a generic medicine, studies in people have been limited to tests to determine that it is bioequivalent to the reference medicine, Viread. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Tenofovir disoproxil Zentiva?

Because 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 Tenofovir disoproxil Zentiva approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Tenofovir disoproxil Zentiva has been shown to have comparable quality and to be bioequivalent to Viread. Therefore, the CHMP's view was that, as for Viread, the benefit outweighs the identified risk. The Committee recommended that Tenofovir disoproxil Zentiva be approved for use in the EU.

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

The company that markets Tenofovir disoproxil Zentiva will ensure that all doctors who are expected to prescribe or use the medicine 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 Tenofovir disoproxil Zentiva have also been included in the summary of product characteristics and the package leaflet.

Other information about Tenofovir disoproxil Zentiva

The European Commission granted a marketing authorisation valid throughout the European Union for Tenofovir disoproxil Zentiva on 15 September 2016.

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

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 09-2016.