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EPAR summary for the public

Tenofovir disoproxil Mylan

tenofovir disoproxil

This is a summary of the European public assessment report (EPAR) for Tenofovir disoproxil Mylan. 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 Mylan.

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

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

Tenofovir disoproxil Mylan is used to treat adults and adolescents from 12 years of age infected with human immunodeficiency virus type 1 (HIV 1), a virus that causes acquired immune deficiency syndrome (AIDS). Tenofovir disoproxil Mylan 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 Mylan 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 Mylan is also used to treat chronic (long-term) hepatitis B virus infection in adults and adolescents from 12 years of age. It is used in patients with liver damage but 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).

Tenofovir disoproxil Mylan contains the active substance tenofovir disoproxil. It is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU)

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called Viread. For more information on generic medicines, see the question-and-answer document here.

How is Tenofovir disoproxil Mylan used?

Tenofovir disoproxil Mylan 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 Mylan is available as tablets (245 mg) to be taken by mouth. The usual dose is one tablet 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, see the package leaflet.

How does Tenofovir disoproxil Mylan work?

The active substance in this medicine, 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 reproduce itself in the cells it has infected. Tenofovir disoproxil Mylan, taken in combination with other antiviral medicines, reduces the amount of HIV in the blood and keeps it at a low level. Tenofovir disoproxil Mylan 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.

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 Mylan stops the virus making DNA and prevents it from multiplying and spreading.

How has Tenofovir disoproxil Mylan been studied?

Because Tenofovir disoproxil Mylan 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 Mylan?

Because Tenofovir disoproxil Mylan 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 Mylan approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Tenofovir disoproxil Mylan 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 Mylan be approved for use in the EU.

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

The company that makes Tenofovir disoproxil Mylan will also 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 Mylan have also been included in the summary of product characteristics and the package leaflet.

Other information about Tenofovir disoproxil Mylan

The European Commission granted a marketing authorisation valid throughout the European Union for Tenofovir disoproxil Mylan on 8 December 2016.

The full EPAR for Tenofovir disoproxil Mylan 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 Mylan, 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 12-2016.