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EPAR summary for the public

Emtricitabine/Tenofovir disoproxil Krka d.d.

emtricitabine / tenofovir disoproxil

This is a summary of the European public assessment report (EPAR) for Emtricitabine/Tenofovir disoproxil Krka d.d. 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 Emtricitabine/Tenofovir disoproxil Krka d.d.

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

What is Emtricitabine/Tenofovir disoproxil Krka d.d. and what is it used for?

Emtricitabine/Tenofovir disoproxil Krka d.d. is an antiviral medicine that is used in combination with at least one other antiviral medicine to treat adults infected with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS).

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

How is Emtricitabine/Tenofovir disoproxil Krka d.d. used?

Emtricitabine/Tenofovir disoproxil Krka d.d. can only be obtained with a prescription and treatment should be started by a doctor who has experience in the management of HIV infection.

Emtricitabine/Tenofovir disoproxil Krka d.d. is available as tablets (200 mg emtricitabine and 245 mg tenofovir disoproxil). The recommended dose is one tablet once a day, preferably taken with food. If

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patients 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, see the package leaflet.

How does Emtricitabine/Tenofovir disoproxil Krka d.d. work?

Emtricitabine/Tenofovir disoproxil Krka d.d. 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 reproduce itself in the cells it has infected.

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

How has Emtricitabine/Tenofovir disoproxil Krka d.d. been studied?

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

As for every medicine, the company provided studies on the quality of Emtricitabine/Tenofovir disoproxil Krka d.d. 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 substances in the body and are therefore expected to have the same effect.

What are the benefits and risks of Emtricitabine/Tenofovir disoproxil Krka d.d.?

Because Emtricitabine/Tenofovir disoproxil Krka d.d. 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 Krka d.d. approved?

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

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

The company that markets Emtricitabine/Tenofovir disoproxil Krka d.d. will provide an information pack to doctors which covers the risk of kidney disease with Emtricitabine/Tenofovir disoproxil Krka d.d.

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

Other information about Emtricitabine/Tenofovir disoproxil Krka d.d.

The European Commission granted a marketing authorisation valid throughout the European Union for Emtricitabine/Tenofovir disoproxil Krka d.d. on 28 April 2017.

The full EPAR for Emtricitabine/Tenofovir disoproxil Krka d.d. 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 Emtricitabine/Tenofovir disoproxil Krka d.d., 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 04-2017.