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SCIENCE MEDICINES HEALTH

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

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

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

Emtricitabine/Tenofovir disoproxil Mylan is an HIV medicine that 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 in adolescents with HIV who are resistant to first-line treatments or who cannot take them because of side effects.

Emtricitabine/Tenofovir disoproxil Mylan 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 Mylan contains two active substances, emtricitabine and tenofovir disoproxil. It is a 'generic medicine'. This means that it contains the same active substances 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 Mylan used?

Emtricitabine/Tenofovir disoproxil Mylan 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 Mylan is available as tablets (200 mg emtricitabine and 245 mg tenofovir disoproxil). The recommended dose for treating or preventing HIV-1 infection is one tablet once a day, preferably taken with food. If 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 about using Emtricitabine/Tenofovir disoproxil Mylan, see the package leaflet or contact your doctor or pharmacist.



How does Emtricitabine/Tenofovir disoproxil Mylan work?

Emtricitabine/Tenofovir disoproxil Mylan 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.

For the treatment of HIV-infection, Emtricitabine/Tenofovir disoproxil Mylan, 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 Mylan does not cure HIV infection or AIDS, but it holds 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 Mylan 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.

How has Emtricitabine/Tenofovir disoproxil Mylan 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 Mylan.

As for every medicine, the company provided studies on the quality of Emtricitabine/Tenofovir disoproxil Mylan. 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 Mylan?

Because Emtricitabine/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 Emtricitabine/Tenofovir disoproxil Mylan authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Emtricitabine/Tenofovir disoproxil Mylan has been shown to have comparable quality and to be bioequivalent to Truvada. Therefore, the Agency's view was that, as for Truvada, the benefit of Emtricitabine/Tenofovir disoproxil Mylan outweighs the identified risk 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 Mylan?

The company that markets Emtricitabine/Tenofovir disoproxil Mylan will provide an information pack to doctors which covers the potential harmful effects of Emtricitabine/Tenofovir disoproxil Mylan on kidney function and information about use 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 Mylan 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 Mylan are continuously monitored. Side effects reported with Emtricitabine/Tenofovir disoproxil Mylan are carefully evaluated and any necessary action taken to protect patients.

Other information about Emtricitabine/Tenofovir disoproxil Mylan

Emtricitabine/Tenofovir disoproxil Mylan received a marketing authorisation valid throughout the EU on 16 December 2016.

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

This overview was last updated in 01-2019.