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Emtricitabine / Tenofovir alafenamide Viatris (emtricitabine / tenofovir alafenamide)

An overview of Emtricitabine / Tenofovir alafenamide Viatris and why it is authorised in the EU

What is Emtricitabine / Tenofovir alafenamide Viatris and what is it used for?

Emtricitabine / Tenofovir alafenamide Viatris is an antiviral medicine used in combination with other medicines to treat individuals infected with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS). It is used in adults and adolescents aged 12 years and older who weigh at least 35 kg.

Emtricitabine / Tenofovir alafenamide Viatris contains the active substances emtricitabine and tenofovir alafenamide and is a 'generic medicine'. This means that Emtricitabine / Tenofovir alafenamide Viatris contains the same active substances and works in the same way as a 'reference medicine' already authorised in the EU. The reference medicine for Emtricitabine / Tenofovir alafenamide Viatris is Descovy. For more information on generic medicines, see the question-and-answer document here.

How is Emtricitabine / Tenofovir alafenamide Viatris used?

Emtricitabine / Tenofovir alafenamide Viatris can only be obtained with a prescription and treatment should be started by a doctor experienced in managing people with HIV infection.

The medicine is available as tablets to be taken by mouth once a day.

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

How does Emtricitabine / Tenofovir alafenamide Viatris work?

Tenofovir alafenamide is a 'prodrug', meaning that it is converted into the active substance tenofovir in the body. Tenofovir and emtricitabine are antiviral agents called reverse transcriptase inhibitors. They block the activity of reverse transcriptase, an enzyme made by the virus that allows it to reproduce itself in the cells it has infected. By blocking reverse transcriptase, Emtricitabine / Tenofovir alafenamide Viatris reduces the amount of HIV in the blood and keeps it at a low level. It does not cure

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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.

How has Emtricitabine / Tenofovir alafenamide Viatris been studied?

Studies on the benefits and risks of the active substance in the authorised use have already been carried out with the reference medicine, Descovy, and do not need to be repeated for Emtricitabine / Tenofovir alafenamide Viatris.

As for every medicine, the company provided studies on the quality of Emtricitabine / Tenofovir alafenamide Viatris. The company also carried out 3 studies 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 alafenamide Viatris?

Because Emtricitabine / Tenofovir alafenamide Viatris 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 alafenamide Viatris authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Emtricitabine / Tenofovir alafenamide Viatris has been shown to have comparable quality and to be bioequivalent to Descovy. Therefore, the Agency's view was that, as for Descovy, the benefits of Emtricitabine / Tenofovir alafenamide Viatris 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 alafenamide Viatris?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Emtricitabine / Tenofovir alafenamide Viatris have been included in the summary of product characteristics and the package leaflet. Any additional measures in place for Descovy also apply to Emtricitabine / Tenofovir alafenamide Viatris where appropriate.

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

Other information about Emtricitabine / Tenofovir alafenamide Viatris

Emtricitabine / Tenofovir alafenamide Viatris received a marketing authorisation valid throughout the EU on 18 July 2025.

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

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