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Emtricitabine / Rilpivirine / Tenofovir Alafenamide Viatris (*emtricitabine / rilpivirine / tenofovir alafenamide*)

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

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

Emtricitabine / Rilpivirine / Tenofovir Alafenamide Viatris is an antiviral medicine used in combination with other medicines to treat people 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 / Rilpivirine / Tenofovir Alafenamide Viatris contains the active substances emtricitabine / rilpivirine / tenofovir and is a 'generic medicine'. This means that this medicine contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU. The reference medicine for Emtricitabine / Rilpivirine / Tenofovir Alafenamide Viatris is Odefsey. For more information on generic medicines, see the question-and-answer document here.

How is Emtricitabine / Rilpivirine / Tenofovir Alafenamide Viatris used?

Emtricitabine / Rilpivirine / 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 daily with food.

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

How does Emtricitabine / Rilpivirine / Tenofovir Alafenamide Viatris work?

Emtricitabine / Rilpivirine / Tenofovir Alafenamide Viatris contains three active substances. Tenofovir alafenamide is a 'prodrug' of tenofovir, meaning that it is converted into the active substance tenofovir in the body. Tenofovir and emtricitabine are related antiviral agents called reverse transcriptase inhibitors. Rilpivirine is an antiviral agent called non-nucleoside reverse transcriptase inhibitor.

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All three active substances block the activity of reverse transcriptase, a virus enzyme that allows HIV-1 to replicate in the cells it has infected. By blocking this enzyme, this medicine reduces the amount of HIV-1 in the blood and keeps it at a low level.

Emtricitabine / Rilpivirine / Tenofovir Alafenamide Viatris does not cure HIV-1 infection or AIDS, but it may delay the damage to the immune system and the development of infections and diseases associated with AIDS.

How has Emtricitabine / Rilpivirine / Tenofovir Alafenamide Viatris been studied?

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

As for every medicine, the company provided studies on the quality of Emtricitabine / Rilpivirine / Tenofovir Alafenamide Viatris. 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 / Rilpivirine / Tenofovir Alafenamide Viatris?

Because Emtricitabine / Rilpivirine / 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 / Rilpivirine / Tenofovir Alafenamide Viatris authorised in the EU?

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

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

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

Other information about Emtricitabine / Rilpivirine / Tenofovir Alafenamide Viatris

Emtricitabine / Rilpivirine / Tenofovir Alafenamide Viatris received a marketing authorisation valid throughout the EU on 19 August 2025.

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

This overview was last updated in 08-2025.