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EPAR summary for the public

Odefsey

emtricitabine / rilpivirine / tenofovir alafenamide

This is a summary of the European public assessment report (EPAR) for Odefsey. 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 Odefsey.

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

What is Odefsey and what is it used for?

Odefsey is an antiviral medicine used to treat adults and adolescents (aged over 12 years and weighing at least 35 kg) infected with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS).

Odefsey contains the active substances emtricitabine, rilpivirine and tenofovir alafenamide. It is only used in patients where the virus has not developed resistance to a class of HIV medicines called non-nucleoside reverse transcriptase inhibitors, tenofovir or emtricitabine, and who have HIV levels in the blood (viral load) of no more than 100,000 HIV-1 RNA copies/ml.

How is Odefsey used?

The medicine can only be obtained with a prescription and treatment should be started by a doctor who is experienced in managing HIV infection. Odefsey is available as tablets, each containing 200 mg emtricitabine, 25 mg rilpivirine, and 25 mg tenofovir alafenamide. The recommended dose is one tablet a day, taken with food.

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How does Odefsey work?

Odefsey 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.

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, Odefsey reduces the amount of HIV-1 in the blood and keeps it at a low level.

Odefsey 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.

What benefits of Odefsey have been shown in studies?

The combination of active substances in Odefsey (emtricitabine, rilpivirine and tenofovir) is already approved in the EU as Eviplera to treat HIV-1 infection, although in Eviplera tenofovir is present as tenofovir disoproxil whereas in Odefsey it is present as tenofovir alafenamide.

To support the use of tenofovir alafenamide, the company provided data from studies showing that combination medicines containing tenofovir alafenamide are as effective in reducing the amount of HIV-1 in the blood as those containing tenofovir disoproxil.

In addition, to support its application, the company performed a 'bioequivalence' study comparing Odefsey with two other HIV medicines: Edurant (rilpivirine) and Genvoya (elvitegravir, cobicistat, emtricitabine and tenofovir alafenamide). This study showed that Odefsey produces the same levels of rilpivirine in the body as Edurant, and the same levels of emtricitabine and tenofovir alafenamide as Genvoya. This means that the effects of these components in Odefsey should be similar to their effects in other medicines.

What are the risks associated with Odefsey?

The most common side effects seen with the active substance rilpivirine and with the combination of emtricitabine and tenofovir alafenamide (which may affect more than 1 in 10 people) are headache, dizziness and nausea (feeling sick). Very common side effects with rilpivirine also include increased cholesterol levels (total cholesterol and LDL-cholesterol), insomnia (difficulty sleeping) and increased liver and pancreas enzymes. For the full list of all side effects, see the package leaflet.

Odefsey must not be used with the following medicines as they may lead to reduced blood levels of rilpivirine, and thereby reduce the effectiveness of Odefsey:

- carbamazepine, oxcarbazepine, phenobarbital, phenytoin (medicines for epilepsy);
- rifabutin, rifampicin, rifapentine (antibiotics);
- omeprazole, esomeprazole, dexlansoprazole, lansoprazole, pantoprazole, rabeprazole (medicines for reducing stomach acid);
- dexamethasone (a corticosteroid medicine used to treat inflammation and suppress the immune system) except when used as a single dose treatment;
- St John's wort (a herbal preparation used for depression and anxiety).

For the full list of restrictions, see the package leaflet.

Why is Odefsey approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) considered that Odefsey is an alternative treatment option to Eviplera with similar effectiveness. In terms of safety, tenofovir alafenamide is effective at a lower dose than tenofovir disoproxil and may lead to reduced side effects in the kidneys and bones. The CHMP therefore decided that Odefsey's benefits are greater than its risks and recommended that it be approved for use in the EU.

What measures are being taken to ensure the safe and effective use of Odefsey?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Odefsey have been included in the summary of product characteristics and the package leaflet.

Other information about Odefsey

The European Commission granted a marketing authorisation valid throughout the European Union for Odefsey on 21. June 2016.

The full EPAR for Odefsey 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 Odefsey, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 06-2016.