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EPAR summary for the public

Descovy

emtricitabine / tenofovir alafenamide

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

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

What is Descovy and what is it used for?

Descovy 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 over 12 years and who weigh at least 35 kg.

Descovy contains the active substances emtricitabine and tenofovir alafenamide.

How is Descovy used?

Descovy can only be obtained with a prescription and treatment should be started by a doctor experienced in managing HIV infection.

Descovy is available as tablets, each containing 200 mg of emtricitabine and either 10 or 25 mg of tenofovir alafenamide. The recommended dose is one tablet per day, and the strength of Descovy tablet chosen by the doctor depends on which other medicines it is given with. For further information, see the summary of product characteristics (also part of the EPAR).

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How does Descovy work?

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. 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, Descovy reduces the amount of HIV in the blood and keeps it at a low level. It does not cure 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.

What benefits of Descovy have been shown in studies?

The active substances in Descovy (emtricitabine and tenofovir alafenamide) are already approved to treat HIV infection together with two other active substances (elvitegravir and cobicistat) as part of the combination medicine Genvoya. The company therefore presented data from the studies previously used to approve Genvoya, including 2 studies in 1,733 previously untreated adults, where around 90% of patients responded to treatment, and another study showing benefit was maintained when patients treated with other effective combinations were switched to Genvoya.

The company also provided data from supporting studies including studies looking at the way Descovy was absorbed in the body. These studies showed that Descovy produces comparable levels of emtricitabine and tenofovir alafenamide in the body to Genvoya.

What are the risks associated with Descovy?

The most common side effect with Descovy (which may affect 1 in 10 people) is nausea (feeling sick). Other common side effects include diarrhoea and headache. For the full list of all side effects and restrictions with Descovy, see the package leaflet.

Why is Descovy approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Descovy's benefits are greater than its risks and recommended that it be approved for use in the EU. Descovy contains tenofovir alafenamide which is effective at a lower dose than the established medicine tenofovir disoproxil and offers the possibility of reduced side effects. Similarly to Genvoya, Descovy offers an alternative option to giving emtricitabine with tenofovir disoproxil

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

A risk management plan has been developed to ensure that Descovy is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Descovy, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Descovy

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

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

This summary was last updated in 04-2016.