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Genvoya (*elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide*)

An overview of Genvoya and why it is authorised in the EU

What is Genvoya and what is it used for?

Genvoya is an antiviral medicine used 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 children from 2 years of age and weighing at least 14 kg whose disease is not expected to be resistant to any of the antiviral substances in Genvoya.

Genvoya contains the active substances elvitegravir, cobicistat, emtricitabine and tenofovir alafenamide.

How is Genvoya used?

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

The medicine is available as tablets at two different strengths. The recommended dose, which depends on the patient's age and weight, is one tablet a day, taken with food.

For more information about using Genvoya, see the package leaflet or contact your doctor or pharmacist.

How does Genvoya work?

Genvoya contains four active substances. Elvitegravir is a type of antiviral agent called an 'integrase inhibitor'. By blocking an enzyme called integrase, elvitegravir stops the virus' genetic material from integrating into the genetic material of the cells it has infected. This reduces the virus' ability to replicate and slows down the spread of infection. Cobicistat increases the level of elvitegravir by slowing its breakdown. This boosts elvitegravir's antiviral effect.

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

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transcriptase inhibitors. They block the activity of reverse transcriptase, a virus enzyme that allows HIV-1 to replicate in the cells it has infected. By blocking reverse transcriptase, Genvoya reduces the amount of HIV-1 in the blood and keeps it at a low level.

Genvoya does not cure HIV-1 infection or AIDS, but it holds off damage to the immune system and the development of infections and diseases associated with AIDS.

What benefits of Genvoya have been shown in studies?

Genvoya was investigated in two main studies involving 1,733 adults infected with HIV-1 who had not been treated previously. In both studies, Genvoya was compared with another antiviral medicine which contained the active substances elvitegravir, cobicistat, emtricitabine and tenofovir disoproxil. The main measure of effectiveness was the reduction of the amount of HIV-1 in the blood. The infection was considered to have responded to treatment if the viral load in the patient's blood was less than 50 copies of HIV-1 RNA/ml. After 48 weeks around 90% of patients treated with either Genvoya (800 of 866 patients) or the comparator (784 of 867 patients) had responded to treatment.

In a supporting study, patients who were being treated with effective HIV treatment either continued with the same treatment or were switched to Genvoya. After 48 weeks a viral load of less than 50 copies/ml was seen in 97% (932 of 959) of patients switched to Genvoya and 93% (444 of 477) of patients who continued with their usual treatment.

In another study, Genvoya was given to adolescents aged 12 to 18 years with HIV-1 infection who had not been treated previously. The viral load was reduced to less than 50 copies/ml after 24 weeks in 90% (45 of 50) of patients.

This study also involved children below 12 years of age who were being treated with effective HIV treatment and who were switched to Genvoya. In 23 children aged 8 to 11 years weighing at least 25 kg, the viral load remained below 50 copies/ml after 48 weeks of treatment with Genvoya at the same dose as that used in adults. In children aged at least 2 years and weighing between 14 kg and less than 25 kg, the viral load remained below 50 copies/ml in 96% (26 of 27) of patients after 48 weeks of treatment with Genvoya at a lower dose than that used in adults.

What are the risks associated with Genvoya?

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

Genvoya must not be taken with certain other medicines because of the possibility of harmful interactions. For the full list of restrictions, see the package leaflet.

Why is Genvoya authorised in the EU?

In studies, the effectiveness of Genvoya was high in patients aged at least 2 years of age, and in adults it was comparable to that of a medicine containing elvitegravir, cobicistat, emtricitabine and tenofovir disoproxil.

Three of the active substances, elvitegravir, cobicistat and emtricitabine, have already been shown to be effective. The fourth, tenofovir alafenamide, is effective at a lower dose than the established medicine tenofovir disoproxil and offers the possibility of reduced side effects. The European Medicines Agency also considered that combining the medicines in a single tablet simplifies treatment.

Genvoya's side effects were similar to those of the individual active substances. In adults, tenofovir alafenamide had a milder effect on the kidney than tenofovir disoproxil. A possible risk of bone density loss in young children given tenofovir alafenamide could be minimised with regular monitoring during treatment.

The Agency therefore decided that Genvoya's benefits are greater than its risks and it can be authorised for use in the EU.

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

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

Other information about Genvoya

Genvoya received a marketing authorisation valid throughout the EU on 19 November 2015.

Further information on Genvoya can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/genvoya.

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