



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Biktarvy (*bictegravir / emtricitabine / tenofovir alafenamide*)

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

What is Biktarvy and what is it used for?

Biktarvy is an antiviral medicine used to treat adults and children from 2 years of age and weighing at least 14 kg infected with human immunodeficiency virus 1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS).

Biktarvy contains the active substances bictegravir, emtricitabine and tenofovir alafenamide. It is only used in patients where the virus has not developed resistance to a class of HIV medicines called integrase inhibitors or to tenofovir or emtricitabine.

How is Biktarvy used?

Biktarvy can only be obtained with a prescription and treatment should be started by a doctor who has experience in the management of HIV infection.

Biktarvy is available as tablets to be taken by mouth once daily, containing either 50 mg bictegravir, 200 mg emtricitabine and 25 mg tenofovir alafenamide or 30 mg bictegravir, 120 mg emtricitabine and 15 mg tenofovir alafenamide. The recommended dose depends on the patient's weight. For more information about using Biktarvy, see the package leaflet or contact your doctor or pharmacist.

How does Biktarvy work?

Biktarvy contains three active substances which work in different ways against HIV:

- bictegravir is a type of antiviral agent called an 'integrase inhibitor'. It blocks an enzyme called integrase that is needed by the HIV virus to make new copies of itself in the body.
- emtricitabine is a nucleotide reverse transcriptase inhibitor (NRTI), which means that it blocks the activity of reverse transcriptase, another enzyme of the virus that allows it to reproduce itself.

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

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- tenofovir alafenamide is a 'prodrug' of tenofovir, meaning that it is converted into the active substance tenofovir in the body. Tenofovir is another type of NRTI and it works in the same way as emtricitabine.

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

What benefits of Biktarvy have been shown in studies?

The benefits of Biktarvy in the treatment of HIV infection were investigated in five main studies.

Two studies involved adults infected with HIV-1 who had not been treated previously, and looked at the numbers whose viral load (the amount of HIV-1 in the blood) was reduced to less than 50 copies per ml after 48 weeks of treatment. In the first study, Biktarvy was compared with another antiviral medicine containing abacavir, dolutegravir and lamivudine in 629 patients. Overall, 92% (290 out of 314) of patients taking Biktarvy achieved viral load reduction, compared with 93% (293 out of 315) of patients who achieved it with the comparator. The second study compared Biktarvy with dolutegravir plus emtricitabine/tenofovir alafenamide in 645 patients: 89% (286 out of 320) of patients taking Biktarvy achieved satisfactory viral load reduction, compared with 93% (302 out of 325) of patients on the comparator.

Two other studies involved previously treated patients in whom the viral load was already lower than 50 copies per ml, and looked at whether it increased above this level 48 weeks after patients were switched from their previous HIV treatment to Biktarvy. In one study, the percentage of patients with viral load greater than or equal to 50 copies/ml was 1% (3 out of 282) of patients who switched to Biktarvy, compared with 0.5% (1 out of 281) of patients who stayed on their previous treatment (dolutegravir, abacavir, lamivudine). In the second study, the viral load went above the threshold in 2% (5 out of 290) of patients switched to Biktarvy, and in 2% (5 out of 287) of patients who stayed on their previous treatment ('boosted' atazanavir or darunavir plus either emtricitabine/tenofovir or abacavir/lamivudine).

An additional study involved children above 2 years of age and weighing more than 14 kg. The viral load was already lower than 50 copies per ml, and the study looked at whether it increased above this level after patients were switched from their previous HIV treatment to Biktarvy. After 48 weeks of treatment with Biktarvy, over 90% of patients maintained the low viral load. Based on additional data on the way the medicine is distributed in the body, Biktarvy is expected to be as effective in children as it is in adults.

What are the risks associated with Biktarvy?

The most common side effects with Biktarvy (which may affect around 1 in 20 people) are headache, diarrhoea and nausea (feeling sick). For the full list of side effects of Biktarvy, see the package leaflet.

Biktarvy must not be used together with rifampicin (an antibiotic) or with St. John's wort (a herbal medicine used for treating depression). For the full list of restrictions, see the package leaflet.

Why is Biktarvy authorised in the EU?

Biktarvy was shown to be as effective as comparator antiviral medicines in adults, and is expected to be equally effective in children. Side effects were similar to those of medicines of the same class. The European Medicines Agency therefore decided that Biktarvy'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 Biktarvy?

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

As for all medicines, data on the use of Biktarvy are continuously monitored. Side effects reported with Biktarvy are carefully evaluated and any necessary action taken to protect patients.

Other information about Biktarvy

Biktarvy received a marketing authorisation valid throughout the EU on 21 June 2018.

Further information on Biktarvy can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/biktarvy

This overview was last updated in 10-2022.