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Dovato (*dolutegravir / lamivudine*)

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

What is Dovato and what is it used for?

Dovato is a medicine for treating infection with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS). It is used to treat adults and adolescents over 12 years old who weigh at least 40 kg.

This medicine contains the active substances dolutegravir and lamivudine and is used to treat infections that are not resistant to medicines of the same class as dolutegravir or to lamivudine.

How is Dovato used?

Dovato can only be obtained with a prescription and should be prescribed by a doctor who is experienced in managing HIV infection.

Dovato is available as tablets containing 50 mg of dolutegravir and 300 mg of lamivudine. The recommended dose is one tablet once a day. For more information about using Dovato, see the package leaflet or contact your doctor or pharmacist.

How does Dovato work?

The two active substances in Dovato, dolutegravir and lamivudine, block the activity of enzymes that the virus uses to make new copies of itself in the body. Dolutegravir stops the activity of an enzyme called integrase (and is known as an integrase inhibitor), while lamivudine stops the activity of another enzyme called reverse transcriptase (and is known as a nucleoside reverse transcriptase inhibitor or NRTI).

Both active substances have already been authorised in the EU as separate tablets: dolutegravir in 2014 and lamivudine in 1996.

Dovato does not cure HIV infection, but it reduces the amount of virus in the body and keeps it at a low level. This holds off damage to the immune system and the development of infections and diseases associated with AIDS.

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What benefits of Dovato have been shown in studies?

Two main studies, involving 1,441 patients, have shown that the combination of the two active substances in Dovato is as effective at lowering the amount of HIV in the blood as a triple combination therapy (dolutegravir plus tenofovir plus emtricitabine).

In these studies, 91% of patients with HIV-1 who took the Dovato combination no longer had detectable levels of HIV (below 50 copies per ml) after 48 weeks compared with 93% of those who were taking the triple combination. In both studies there were no cases of resistance to treatment after 48 weeks.

What are the risks associated with Dovato?

The most common side effects with Dovato (which may affect up to 1 in 10 people) are headache, diarrhoea, nausea (feeling sick) and difficulty sleeping. The most common serious side effects (which may affect up to 1 in 100 people) are allergic reactions, including rash and severe liver problems.

Dovato must not be used together with certain medicines such as fampridine (a multiple sclerosis medicine, also called dalfampridine), as this may increase the level of such medicines in the body, resulting in serious side effects.

For the full list of side effects and restrictions, see the package leaflet.

Why is Dovato authorised in the EU?

Triple combination therapy is used for HIV treatment to reduce the chance of the virus becoming resistant to treatment. In two main studies, the Dovato combination was just as effective as a triple combination in patients with HIV-1, with no cases of resistance developing in these patients. Furthermore, both active substances are available in a single tablet and are acceptably safe.

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

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

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

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

Other information about Dovato

Dovato received a marketing authorisation valid throughout the EU on 1 July 2019.

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

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