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# Delstrigo (*doravirine / lamivudine / tenofovir disoproxil*)

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

## What is Delstrigo and what is it used for?

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

The medicine is only used in patients where the virus has not developed resistance to medicines that work in the same way as Delstrigo's active substances.

It is only used in adolescents if other HIV medicines without tenofovir disoproxil cannot be used because of side effects.

Delstrigo contains the active substances doravirine, lamivudine and tenofovir disoproxil.

## How is Delstrigo used?

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

Delstrigo is available as tablets, each containing 100 mg of doravirine, 300 mg of lamivudine and 245 mg of tenofovir disoproxil. The recommended dose is one tablet daily.

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

## How does Delstrigo work?

All three active substances in Delstrigo block the activity of reverse transcriptase, a virus enzyme that allows HIV to reproduce itself in the cells it has infected. Doravirine is a non-nucleoside reverse transcriptase inhibitor (NNRTI) and lamivudine is a nucleoside reverse transcriptase inhibitor (NRTI). Tenofovir disoproxil is a 'prodrug' of tenofovir, meaning that it is converted in the body to the active substance tenofovir. Tenofovir is a nucleotide reverse transcriptase inhibitor.

Delstrigo keeps the amount of HIV in the blood at a low level. It does not cure HIV infection or AIDS but it holds off the damage to the immune system and the development of infections and diseases associated with AIDS.

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## What benefits of Delstrigo have been shown in studies?

Delstrigo was as effective at keeping HIV infection under control as a similar HIV combination treatment in a main study involving adult patients with HIV infection who had not been treated before. In the study with 728 adult patients, 84% of patients treated with Delstrigo had undetectable levels of HIV in their blood (fewer than 40 copies/ml) after 48 weeks of treatment compared with 80% of patients given a combination of efavirenz, emtricitabine and tenofovir disoproxil.

A second study that included 43 adolescent patients aged 12 to 18 years who had been previously treated for HIV showed that Delstrigo was also effective at keeping viral load below 40 copies/ml in this age group; 95% (41 of 43 patients) had undetectable levels after 24 weeks, and 93% (40 of 43 patients) had undetectable levels after 48 weeks.

## What are the risks associated with Delstrigo?

The most common side effects with doravirine (which may affect up to 1 in 10 people) are nausea (feeling sick) and headache.

Delstrigo must not be used with certain medicines that may reduce its effectiveness. For the full list of side effects and restrictions with Delstrigo, see the package leaflet.

## Why is Delstrigo authorised in the EU?

Delstrigo was shown to be effective at keeping HIV infection under control in both adults and adolescent from 12 years of age. In addition, Delstrigo's side effects are mostly mild.

The European Medicines Agency therefore decided that Delstrigo'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 Delstrigo?

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

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

## Other information about Delstrigo

Delstrigo received a marketing authorisation valid throughout the EU on 22 November 2018.

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

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