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Pifeltro (*doravirine*)

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

What is Pifeltro and what is it used for?

Pifeltro 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). Pifeltro is used together with other antiviral medicines.

It is only used in patients where the virus has not developed resistance to medicines that work in the same way as Pifeltro.

Pifeltro contains the active substance doravirine.

How is Pifeltro used?

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

Pifeltro is available as tablets (100 mg). The recommended dose is one tablet daily.

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

How does Pifeltro work?

The active substance in Pifeltro, doravirine, is a non-nucleoside reverse transcriptase inhibitor (NNRTI). Doravirine blocks the activity of reverse transcriptase, a virus enzyme that allows HIV to reproduce itself in the cells it has infected.

Pifeltro helps keep the amount of HIV in the blood at a low level. It does not cure HIV infection or AIDS but, when used in combination with other antivirals, it holds off the damage to the immune system and the development of infections and diseases associated with AIDS.

What benefits of Pifeltro have been shown in studies?

Studies showed that Pifeltro taken with other antivirals was as effective at keeping HIV infection under control as standard HIV combination treatments.

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In a study of 766 adult patients, 83% of patients taking Pifeltro (together with either emtricitabine and tenofovir disoproxil or abacavir and lamivudine) had undetectable levels of HIV in their blood (fewer than 40 copies/ml) after 48 weeks of treatment. This compares with 79% of patients taking a standard combination of darunavir plus ritonavir (together with either emtricitabine and tenofovir disoproxil or abacavir and lamivudine).

In a second study with 728 adult patients, 84% of patients treated with Pifeltro in combination with tenofovir disoproxil and lamivudine had undetectable HIV levels by 48 weeks compared with 80% of patients given a combination of efavirenz, tenofovir disoproxil and emtricitabine.

A third study that included 43 adolescent patients aged 12 to 18 years who had been previously treated for HIV showed that Pifeltro (together with tenofovir disoproxil and lamivudine) 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 Pifeltro?

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

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

Why is Pifeltro authorised in the EU?

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

The European Medicines Agency therefore decided that Pifeltro'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 Pifeltro?

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

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

Other information about Pifeltro

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

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

This overview was last updated in 03-2022.