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Trogarzo (*ibalizumab*)

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

Medicinal Product no longer authorised

What is Trogarzo and what is it used for?

Trogarzo is a medicine used to treat adults infected with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS). Trogarzo is given with other HIV medicines when none of the standard combinations work to control the infection because the virus is resistant to them (multi-drug resistant HIV).

Trogarzo contains the active substance ibalizumab.

How is Trogarzo used?

The medicine can only be obtained with a prescription. Treatment should be started and monitored by a doctor who is experienced in the treatment of HIV infection.

Trogarzo is available as a solution for infusion (drip) into a vein. Treatment is started with a single infusion of 2,000 mg followed by 800 mg every 2 weeks; if treatment is interrupted, it should be restarted in the same way. Patients should be monitored for at least one hour after the first infusion for any reactions. If a reaction occurs, the infusion should be stopped and patients should receive appropriate treatment.

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

How does Trogarzo work?

The active substance in Trogarzo, ibalizumab, is a monoclonal antibody (a type of protein) designed to attach to CD4, a receptor (target) found on the surface of immune cells called T cells. T cells are the main target of the HIV virus, which it uses as a host to reproduce. By attaching to CD4, ibalizumab prevents the virus from entering the T-cells and reproducing, thereby slowing down the spread of infection.

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

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What benefits of Trogarzo have been shown in studies?

Trogarzo taken with other HIV medicines was shown to be effective at reducing viral load (blood levels of HIV virus) in patients with multi-drug resistant HIV, that is, where standard HIV combination treatments have failed to suppress levels of HIV in the blood sufficiently.

In a main study that included 40 adults with multi-drug resistant HIV whose HIV treatment was failing, levels of HIV virus in the blood were undetectable (fewer than 50 copies/ml) in 43% of patients after 25 weeks of combining standard treatment with Trogarzo.

Similar effects were seen in a second main study with 113 adults, where 44% of patients who had maintenance doses of Trogarzo added to standard treatment had undetectable HIV levels after 25 weeks.

What are the risks associated with Trogarzo?

The most common side effects with Trogarzo (which may affect up to 1 in 10 patients) are rash, diarrhoea, dizziness, headache, nausea (feeling sick), vomiting and tiredness.

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

Why is Trogarzo authorised in the EU?

In patients with multi-drug resistant HIV, treatment options are limited and there is therefore an unmet medical need in this group. Although the studies submitted were small and did not include a direct comparison with other medicines, the results indicate that adding Trogarzo to other medicines could control the virus in these patients. Overall, the safety profile of Trogarzo was considered to be acceptable. The European Medicines Agency therefore decided that Trogarzo'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 Trogarzo?

The company that markets Trogarzo will carry out a study to confirm the benefits of treatment with Trogarzo in patients with multi-drug resistant HIV infection.

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

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

Other information about Trogarzo

Trogarzo received a marketing authorisation valid throughout the EU on 26 September 2019.

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

This overview was last updated in 09-2019.

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