EMA/197378/2020
EMEA/H/C/000338

Trizivir (*abacavir / lamivudine / zidovudine*)

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

What is Trizivir and what is it used for?

Trizivir is used to treat adults who are infected with human immunodeficiency virus (HIV), the virus that causes acquired immune deficiency syndrome (AIDS). It is used to replace treatment with the three active substances (abacavir, lamivudine and zidovudine) taken separately at doses similar to those in Trizivir. Patients should have been taking the three active substances separately for at least 6 weeks before switching to Trizivir.

Trizivir contains three active substances: abacavir, lamivudine and zidovudine.

How is Trizivir used?

Trizivir can only be obtained with a prescription and treatment should be started by a doctor who has experience in managing HIV infection.

Before starting treatment with abacavir, all patients should have a test to find out if they have a gene called 'HLA-B (type 5701)'. Patients with this gene are at an increased risk of having an allergic reaction to abacavir, so they should not take Trizivir.

Trizivir is available as tablets (300 mg abacavir/150 mg lamivudine/300 mg zidovudine). The recommended dose is one tablet twice a day. If patients need to stop taking abacavir, lamivudine or zidovudine, or need to take different doses because of problems with their kidneys, liver or blood, they will need to take medicines containing abacavir, lamivudine or zidovudine separately. For more information about using Trizivir, see the package leaflet or contact your doctor or pharmacist.

How does Trizivir work?

All three active substances in Trizivir, abacavir, lamivudine, and zidovudine, are nucleoside reverse transcriptase inhibitors (NRTIs). They work in similar ways by blocking the activity of reverse transcriptase, an enzyme produced by HIV that allows it to make more copies of itself in the cells it has infected and so spread in the body. Trizivir does not cure HIV infection but it reduces the amount of

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
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

HIV in the blood 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.

All three active substances have been available in the European Union (EU) for a number of years: abacavir has been authorised as Ziagen since 1999, lamivudine has been authorised as Epivir since 1996, and zidovudine has been available in the EU since the mid-1980s.

What benefits of Trizivir have been shown in studies?

No specific clinical studies have been carried out to assess the safety and effectiveness of the combined tablet. The company presented the results of studies with abacavir, lamivudine and zidovudine taken together, which were carried out during the development of Ziagen. In these studies, the combination of the three active substances was shown to be at least as effective as the comparator combinations in keeping viral loads low.

The company also looked at the way the combined tablet was absorbed in the body in comparison with the separate tablets. The combination tablet was absorbed in the body in the same way as the separate tablets.

What are the risks associated with Trizivir?

The most common effects with Trizivir (which may affect more than 1 in 10 people) are headache and nausea (feeling sick). For the full list of side effects of Trizivir, see the package leaflet.

Hypersensitivity reactions (allergic reactions) occur in patients taking Trizivir, usually within the first 6 weeks of treatment, and can be life-threatening. The risk of hypersensitivity is higher in patients who have the HLA-B (type 5701) gene. Symptoms almost always include fever or rash, but also very commonly include nausea, vomiting, diarrhoea, abdominal (belly) pain, headache, blood tests showing signs of liver damage, muscle pain, dyspnoea (difficulty breathing), cough, lethargy (lack of energy) and feeling unwell. Treatment with Trizivir should be stopped promptly if the patient has a hypersensitivity reaction. For more information, see the package leaflet.

Trizivir must not be used in patients who have kidney failure. Because it contains zidovudine, Trizivir must not be used by patients with low neutrophil counts (low levels of a type of white blood cell) or anaemia (low red blood cell counts). For the full list of restrictions, see the package leaflet.

Why is Trizivir authorised in the EU?

The European Medicines Agency noted that reducing the number of tablets that patients need to take may help patients stick to their treatment. The Agency therefore decided that Trizivir'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 Trizivir?

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

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

Other information about Trizivir

Trizivir received a marketing authorisation valid throughout the EU on 28 December 2000.

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

This summary was last updated in 04-2020.