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EPAR summary for the public

Trizivir

abacavir, lamivudine and zidovudine

This document is a summary of the European Public Assessment Report (EPAR) for Trizivir. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Trizivir.

What is Trizivir?

Trizivir is a medicine that contains three active substances: abacavir, lamivudine and zidovudine. It is available as tablets (300 mg/150 mg/300 mg).

What is Trizivir 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 six to eight weeks before switching to Trizivir. Before prescribing Trizivir, doctors should consider the expected improved ability of the patient to stick to their treatment, the expected effectiveness of the medicine, and the risks associated with the active substances.

In patients with high levels of HIV in the blood (above 100,000 copies/ml), the choice of treatment requires special consideration.

Overall, since certain other combination treatments could be more effective, the use of Trizivir should only be considered under special circumstances such as co-infection with tuberculosis (as other HIV treatments can interact with the medicines being taken by the patient).

The medicine can only be obtained with a prescription.

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How is Trizivir used?

Treatment with Trizivir should be started by a doctor who has experience in the management of 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.

The recommended dose of Trizivir 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, see the package leaflet.

How does Trizivir work?

All three active substances in Trizivir, abacavir, lamivudine, and zidovudine, are nucleoside reverse transcriptase inhibitors (NRTIs). They all work in similar ways by blocking the activity of reverse transcriptase, an enzyme produced by HIV that allows it to infect cells and make more viruses. Trizivir reduces the amount of HIV in the blood and keeps it at a low level. Trizivir does not cure HIV infection or AIDS, but it may delay the 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.

How has Trizivir been studied?

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

What benefit has Trizivir shown during the studies?

In the studies carried out for the development of Ziagen, 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 combination tablet was absorbed in the body in the same way as the separate tablets.

What is the risk associated with Trizivir?

The most common effects with Trizivir (seen in more than 1 patient in 10) are headache and nausea (feeling sick). For the full list of all side effects reported with Trizivir, see the package leaflet.

Hypersensitivity reactions (allergic reactions) occur in patients taking Trizivir, usually within the first six 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 pain (stomach ache), headache, signs of liver damage in the blood, myalgia (muscle pain), dyspnoea (difficulty breathing), cough, lethargy

(lack of energy) and malaise (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 has Trizivir been approved?

The CHMP noted that the reduction in the number of tablets that patients need to take may help patients stick to their treatment. It also noted that the benefit of Trizivir has mainly been shown in patients who have had little or no previous HIV treatment and who do not have advanced disease. The Committee decided that Trizivir's benefits are greater than its risks and recommended that it be given marketing authorisation.

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

A risk management plan has been developed to ensure that Trizivir is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Trizivir, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, the company that markets Trizivir provides educational materials for doctors about hypersensitivity reactions with the medicine, including the need to test patients for the HLA-B (type 5701) gene and to remind patients to contact their doctor immediately if they develop symptoms suggestive of hypersensitivity. Patients will also receive an alert card summarising key safety information on hypersensitivity reactions with this medicine.

Other information about Trizivir:

The European Commission granted a marketing authorisation valid throughout the EU for Trizivir on 28 December 2000.

The full EPAR for Trizivir can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Trizivir, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 04-2016.