EMA/546473/2014
EMEA/H/C/002754

EPAR summary for the public

Triumeq

dolutegravir / abacavir / lamivudine

This is a summary of the European public assessment report (EPAR) for Triumeq. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Triumeq.

For practical information about using Triumeq, patients should read the package leaflet or contact their doctor or pharmacist.

What is Triumeq and what is it used for?

Triumeq is an antiviral medicine used to treat patients with human immunodeficiency virus (HIV), the virus that causes acquired immunodeficiency syndrome (AIDS). It is used in patients from 12 years of age and weighing at least 40 kg.

Triumeq contains three active substances: dolutegravir, abacavir and lamivudine.

How is Triumeq used?

Triumeq can only be obtained with a prescription and treatment should be prescribed by a doctor who is experienced in managing HIV infections.

Before starting treatment with Triumeq, 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 Triumeq.

Triumeq is available as tablets (50 mg dolutegravir / 600 mg abacavir /300 mg lamivudine) and the recommended dose is one tablet a day, taken with or without food.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

How does Triumeq work?

One of the active substances in Triumeq, dolutegravir, is an integrase inhibitor. This is an antiviral medicine that blocks an enzyme called integrase that is needed by the HIV virus to make new copies of itself in the body. The other two active substances, abacavir and lamivudine, are nucleoside reverse-transcriptase inhibitors (NRTIs). They both 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.

Triumeq reduces the amount of HIV in the blood and keeps it at a low level. Triumeq 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 in Triumeq are already available in the European Union (EU) as single-component medicines: abacavir has been authorised as Ziagen since 1999, lamivudine as Epivir since 1996, and dolutegravir as Tivicay since January 2014. The combination of abacavir and lamivudine has been authorised as Kivexa since 2004.

What benefits of Triumeq have been shown in studies?

The combination of dolutegravir, abacavir and lamivudine (as found in Triumeq) was evaluated in one main study involving 833 previously untreated patients. Data from this study had already been used in the authorisation of Tivicay.

Patients were either given the Triumeq combination or a different three-drug combination (Atripla) that did not include an integrase inhibitor. The main measure of effectiveness was the response rate, which was the proportion of patients with a reduction of the levels of virus in the blood (viral load) to fewer than 50 copies of HIV RNA per ml. After 48 weeks, 88% of the patients given the combination found in Triumeq (364 out of 414) responded to treatment, compared with 81% of the patients who were given Atripla (338 out of 419). Data from this study collected until week 96 showed that this effect was maintained over time.

The company also looked at the way Triumeq was absorbed in the body in comparison with two separate tablets (dolutegravir and abacavir/lamivudine) containing the three medicines that make it up. Results from this study showed that Triumeq was absorbed into the body in the same way as the separate medicines.

What are the risks associated with Triumeq?

The most common side effects with Triumeq (which may affect more than 1 in 10 people) are insomnia (difficulty sleeping), headache, nausea (feeling sick), diarrhoea and fatigue (tiredness). In patients taking some of the components of Triumeq, certain serious side effects have been seen including hypersensitivity (allergic). For the full list of all side effects reported with Triumeq, see the package leaflet.

Triumeq must not be used together with dofetilide, a medicine used to control cardiac arrhythmia (unstable heartbeat). For the full list of restrictions with Triumeq, see the package leaflet.

Why is Triumeq approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Triumeq's benefits are greater than its risks and recommended that it be approved for use in the EU. The CHMP concluded that the medicine had demonstrated its effectiveness in previously untreated patients, and that similar benefits are expected in patients who have received previous treatment.

The CHMP also noted that giving the combination of dolutegravir, abacavir and lamivudine as a single tablet is an additional treatment option for patients with HIV infection and without the HLA-B (type 5701) gene. Giving the combined medicine rather than the single medicines reduces the number of tablets patients have to take, helping them to adhere to their treatment. The CHMP also considered the fact that Triumeq can be taken with or without food as an additional advantage compared with other similar medicines which have to be taken strictly either with food or on an empty stomach. Regarding Triumeq's safety profile, this was expected to be similar to the safety profile of the single components and comparable to that of other HIV treatments.

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

A risk management plan has been developed to ensure that Triumeq 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 Triumeq, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, the company that markets Triumeq will provide educational material for healthcare professionals expected to prescribe Triumeq that addresses the risk of abacavir-associated hypersensitivity.

Further information can be found in the summary of the risk management plan.

Other information about Triumeq

The European Commission granted a marketing authorisation valid throughout the European Union for Triumeq on 1 September 2014.

The full EPAR and risk management plan summary for Triumeq 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 Triumeq, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in August-2014.