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Triumeq (*dolutegravir / abacavir / lamivudine*)

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

What is Triumeq and what is it used for?

Triumeq is a medicine for treating infection with human immunodeficiency virus (HIV), the virus that causes acquired immunodeficiency syndrome (AIDS). It is used in adults, adolescents and children at least 3 months old who weigh at least 6 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 an allergic reaction to abacavir, so they should not take Triumeq.

Triumeq is available as:

- tablets containing 50 mg dolutegravir, 600 mg abacavir and 300 mg lamivudine for adults, adolescents and children weighing at least 25 kg. The recommended dose is one tablet a day.
- dispersible tablets containing 5 mg dolutegravir, 60 mg abacavir and 30 mg lamivudine for children from the age of 3 months weighing at least 6kg and less than 25 kg. The recommended dose depends on the weight of the patient.

Triumeq can be taken with or without food. For more information about using Triumeq, see the package leaflet or contact your doctor or pharmacist.

How does Triumeq work?

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

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They both work 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.

Triumeq does not cure HIV infection but it reduces the amount of HIV in the body 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 in Triumeq are already available in the EU as single-component medicines: abacavir has been authorised as Ziagen since 1999, lamivudine as Epivir since 1996, and dolutegravir as Tivicay since 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. After 48 weeks, 88% of the patients given Triumeq no longer had detectable levels of HIV (below 50 copies per ml of plasma [the liquid part of the blood]), compared with 81% of the patients who were given Atripla. 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 up Triumeq. Results from this study showed that Triumeq was absorbed in the body in the same way as the separate medicines.

Studies were also carried out to show that recommended doses of tablets and dispersible tablets in children produced levels of active substances in the body that were similar to what is seen in adults.

What are the risks associated with Triumeq?

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

The most common side effects with Triumeq (which may affect more than 1 in 10 people) include insomnia (difficulty sleeping), headache, nausea (feeling sick), diarrhoea and fatigue (tiredness).

Triumeq must not be used together with certain medicines such as fampridine (a multiple sclerosis medicine, also called dalfampridine), as this may increase the level of such medicines in the body, resulting in serious side effects. Serious hypersensitivity reactions (allergic reactions) requiring the patient to stop treatment permanently may occur with Triumeq, especially in people with the HLA-B (type 5701) gene. For the full list of restrictions with Triumeq, see the package leaflet.

Why is Triumeq authorised in the EU?

The European Medicines Agency decided that Triumeq's benefits are greater than its risks and it can be authorised for use in the EU. The Agency concluded that the medicine had demonstrated its effectiveness in previously untreated patients, and that similar benefits are expected in previously treated patients.

The Agency 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. The combined medicine reduces the number of tablets patients have to take, helping them to adhere to their treatment. In addition, the Agency 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. Finally, Triumeq's safety profile 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?

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

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

Other information about Triumeq

Triumeq received a marketing authorisation valid throughout the EU on 1 September 2014.

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

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