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Tivicay (*dolutegravir*)

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

What is Tivicay and what is it used for?

Tivicay is a medicine used together with other medicines to treat adults and children from 4 weeks of age and weighing at least 3 kg who are infected with human immunodeficiency virus (HIV), a virus that causes acquired immune deficiency syndrome (AIDS).

Tivicay contains the active substance dolutegravir.

How is Tivicay used?

Tivicay can only be obtained with a prescription and should be prescribed by a doctor who is experienced in managing HIV infection.

Tivicay is available as tablets and dispersible tablets, which have different doses and should not be interchanged without dose adjustment. The adult dose depends on whether the infection is known or suspected to be resistant to medicines of the class to which Tivicay belongs (integrase inhibitors), and whether patients are also taking certain medicines that decrease the effectiveness of Tivicay.

The dose for children depends on the age and weight of the child; children aged 6 years and above and weighing at least 14 kg are normally given tablets while dispersible tablets must be used in younger children.

Although Tivicay can normally be taken with or without food, patients whose virus is resistant to this class of medicines should take Tivicay with food, as it helps the medicine to be absorbed better.

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

How does Tivicay work?

The active substance in Tivicay, dolutegravir, is an integrase inhibitor. This is an antiviral medicine that blocks an enzyme called integrase that the virus needs to make new copies of itself in the body. Tivicay does not cure HIV infection, but when given with other medicines it reduces the amount of virus 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.

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What benefits of Tivicay have been shown in studies?

Tivicay was effective against HIV-1 in four main studies. The main measure of effectiveness in all the studies was the response rate, which was the proportion of patients with an undetectable level of the virus (below 50 copies per ml).

Two studies involved patients who had not previously been treated for HIV:

- In the first of these, involving 822 patients, Tivicay once daily was compared with raltegravir (another integrase inhibitor), both given in combination with two other HIV medicines of a different class (known as nucleoside reverse transcriptase inhibitors or NRTIs): 88% of those given Tivicay and 85% of those given raltegravir responded after 48 weeks of treatment.
- The second study involved 833 patients given either a combination of Tivicay with two NRTIs or a different three-drug combination (Atripla) that did not include an integrase inhibitor. The response rate at 48 weeks was 88% in those given Tivicay-based treatment compared with 81% in those given Atripla.

Two other studies looked at the effectiveness of Tivicay in patients whose previous HIV treatment had stopped working:

- The first of these involved 724 patients whose previous treatment had not included an integrase inhibitor and whose infection was therefore not expected to be resistant to this class of medicines. Patients were treated with a combination of HIV medicines that included either Tivicay or raltegravir. Response rate at 48 weeks was 71% in patients given treatment based on Tivicay and 64% in those given treatment based on raltegravir.
- The second study involved 183 patients with infection resistant to previous treatment that had involved an integrase inhibitor (i.e., their infection was resistant to several classes of medicine, including previous integrase inhibitors). Adding Tivicay twice daily to other treatment resulted in a response rate of 69% after 24 weeks of therapy.

Studies were also carried out to show that recommended doses of tablets and dispersible tablets in children produced levels of the active substance in the body that are effective in controlling the virus.

What are the risks associated with Tivicay?

The most common side effects with Tivicay (which may affect more than 1 in 10 people) are nausea (feeling sick), diarrhoea, and headache. More serious adverse effects that have been reported include an uncommon but severe hypersensitivity (allergic) reaction with rash and possible effects on the liver. For the full list of side effects of Tivicay, see the package leaflet.

Tivicay 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.

For the full list of restrictions, see the package leaflet.

Why is Tivicay authorised in the EU?

The European Medicines Agency noted that Tivicay had demonstrated effectiveness in both untreated and previously treated patients, including those with resistance to integrase inhibitors. The medicine

was generally well tolerated, although the Agency noted the possible risk of infrequent but severe hypersensitivity reactions.

The European Medicines Agency therefore decided that Tivicay'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 Tivicay?

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

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

Other information about Tivicay

Tivicay received a marketing authorisation valid throughout the EU on 16 January 2014.

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

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