EMA/353154/2018
EMEA/H/C/004391

Symtuza (*darunavir / cobicistat / emtricitabine / tenofovir alafenamide*)

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

What is Symtuza and what is it used for?

Symtuza is an antiviral medicine used to treat human immunodeficiency virus type 1 (HIV-1) in adults and adolescents aged from 12 years (and weighing at least 40 kg). HIV-1 is a virus that causes acquired immune deficiency syndrome (AIDS).

Symtuza contains the active substances darunavir, cobicistat, emtricitabine and tenofovir alafenamide.

How is Symtuza used?

Symtuza can only be obtained with a prescription and treatment should be started by a doctor who is experienced in managing HIV infection.

Symtuza is available as tablets, each containing 800 mg darunavir, 150 mg cobicistat, 200 mg emtricitabine and 10 mg tenofovir alafenamide. The recommended dose is one tablet a day, taken with food.

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

How does Symtuza work?

Symtuza contains four active substances which work in different ways against HIV:

- Darunavir is a type of antiviral agent called a 'protease inhibitor'. It blocks protease, an enzyme of the virus that allows it to reproduce itself in the cells it has infected. By blocking protease, Symtuza reduces the amount of HIV-1 in the blood and keeps it at a low level.
- Cobicistat acts as a 'booster' to increase the effects of darunavir, by slowing down the breakdown of darunavir and therefore prolonging its antiviral activity in the body.

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- Tenofovir alafenamide is a ‘prodrug’ of tenofovir, meaning that it is converted into the active substance tenofovir in the body. Tenofovir is a reverse transcriptase inhibitor, which means that it blocks the activity of the enzyme, reverse transcriptase, that the virus needs to reproduce itself.
- Emtricitabine is also a reverse transcriptase inhibitor and it works in the same way as tenofovir.

Symtuza does not cure HIV-1 infection or AIDS, but it may hold off the damage to the immune system and the development of infections and diseases associated with AIDS.

What benefits of Symtuza have been shown in studies?

Because the individual active substances of Symtuza have previously been shown to be effective and are authorised for use in the treatment of HIV infection, studies were mainly carried out to show that Symtuza produced similar levels of active substances in the blood as the active substances given separately.

In addition, one main study compared Symtuza with another antiviral medicine containing darunavir, cobicistat, emtricitabine and tenofovir disoproxil in 153 adult patients with HIV who had not been previously treated. Effectiveness was measured by a reduction in viral load (the amount of HIV-1 in the blood) to less than 50 copies/ml. Overall, 75% of patients taking Symtuza (77 patients out of 103) achieved this reduction after 24 weeks of treatment, which was similar to the 74% (37 of 50) of patients who achieved it with the comparator.

What are the risks associated with Symtuza?

The most common side effects with Symtuza (which may affect more than 1 in 10 people) are diarrhoea, headache and rash. For the full list of side effects reported with Symtuza, see the package leaflet.

Symtuza must not be taken by patients with severely reduced liver function. It must also not be taken with certain medicines that can reduce the effectiveness of Symtuza, as well as medicines that can increase the risk of serious side effects. For more information on the medicines that should not be taken with Symtuza, see the package leaflet.

Why is Symtuza authorised in the EU?

The active substances in Symtuza have already been shown to be effective when used individually, and combining them in a single tablet simplifies treatment. Symtuza was also as effective as a similar combination medicine containing tenofovir disoproxil in place of tenofovir alafenamide. Because tenofovir alafenamide is effective at a lower dose than tenofovir disoproxil, Symtuza offers the possibility of reduced side effects.

The European Medicines Agency decided that Symtuza’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 Symtuza?

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

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

Other information about Symtuza

Symtuza received a marketing authorisation valid throughout the EU on 21 September 2017.

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

This overview was last updated in 07-2019.