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EPAR summary for the public

Telzir

fosamprenavir

This document is a summary of the European public assessment report (EPAR) for Telzir. 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 Telzir.

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

What is Telzir and what is it used for?

Telzir is an antivral medicine for treating patients aged 6 years or above who are infected with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS).

Telzir is used with in combination with ritonavir and other antiviral medicines. It contains the active substance fosamprenavir.

How is Telzir used?

Telzir is available as tablets (700 mg) and as an oral suspension (50 mg/ml) to be taken by mouth. The recommended dose for adults (aged 18 years or over) and for patients aged between 6 and 18 years who weigh more than 39 kg is 700 mg twice a day. In patients aged between 6 and 18 years who weigh between 25 and 39 kg, the dose depends on body weight. There is no recommended dose for patients below 18 years who weigh less than 25 kg.

Telzir tablets can be taken with or without food. The oral suspension should be taken without food in adults, but in younger patients it should be taken with food in order to hide the taste and help them stick to treatment. In adults, each dose of Telzir must be given with 100 mg ritonavir, twice a day. In younger patients, the dose of ritonavir depends on body weight.

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Adults with liver problems should take a reduced dose of Telzir and be closely monitored for safety and their response to treatment.

For patients who have taken medicines to treat their HIV infection before and did not respond to that treatment, doctors should only prescribe Telzir once they have looked at the antiviral medicines the patient has taken before and assessed the likelihood of the virus's response to any new antiviral medicines that might be prescribed.

Treatment with Telzir should be started by a doctor who has experience in the management of HIV infection. The medicine can only be obtained with a prescription.

How does Telzir work?

The active substance in Telzir, fosamprenavir, is a 'prodrug' of the protease inhibitor amprenavir, which means that it is converted into amprenavir in the body. Amprenavir has been authorised in the European Union (EU) since October 2000 as Agenerase. Amprenavir blocks an enzyme called protease, which is involved in the reproduction of HIV. When the enzyme is blocked, the virus does not reproduce normally, slowing down the spread of infection.

Telzir, taken in combination with other antiviral medicines, reduces the amount of HIV in the blood and keeps it at a low level. Telzir does not cure HIV infection or AIDS, but it can hold off the damage to the immune system and the development of infections and diseases associated with AIDS.

Ritonavir, another protease inhibitor, is used with Telzir as a 'booster'. It slows down the rate at which fosamprenavir is broken down, helping to increase levels of fosamprenavir in the blood.

What benefits of Telzir have been shown in studies?

Telzir has been studied in three main studies involving 1,862 adults. Two of the studies in previously untreated patients showed that Telzir in combination with other antiviral medicines was as effective as a comparator medicine.

In one study after 48 weeks of treatment, 69% of previously untreated adults taking ritonavir-boosted Telzir (221 out of 322) and 68% of those taking nelfinavir (221 out of 327) had viral loads below 400 copies/ml. Similar results were seen in the other study comparing Telzir with lopinavir, with around three-quarters of both groups of previously untreated patients having viral loads below 400 copies/ml.

In a third study in patients who had been treated before, Telzir was less effective than the comparator medicine lopinavir, with patients taking lopinavir having larger reductions in viral loads over the first 48 weeks.

Patients in these three adult studies also took two reverse-transcriptase inhibitors (another type of antiviral medicine) in addition to Telzir or the medicine Telzir was being compared with.

A similar benefit has also been seen in one main study including 57 children aged between 2 and 18 years. However, there were too few patients aged below 6 years to support the use of Telzir in this age group.

What are the risks associated with Telzir?

The most common side effects in adults taking Telzir (seen in more than 1 patient in 10) are diarrhoea and increases in the levels of triglycerides (a type of fat) in the blood. Similar side effects are seen in younger patients. For the full list of all side effects reported with Telzir, see the package leaflet.

Telzir should not be used in people who are hypersensitive (allergic) to fosamprenavir, amprenavir, any of the other ingredients, or ritonavir. Telzir must not be used in patients who are taking paritaprevir (for hepatitis C), simvastatin or lovastatin (for lowering blood cholesterol), rifampicin (for tuberculosis), St John's wort (a herbal preparation for depression and anxiety), or medicines that are broken down in the same way as Telzir or ritonavir and are harmful at high levels in the blood. As Telzir is converted into amprenavir in the body, it must not be given at the same time as other medicines containing amprenavir.

Why is Telzir approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that Telzir, which contains a prodrug of amprenavir, provides an advantage for patients, as the number of tablets they need to take is reduced when compared to the number of Agenerase capsules that they would need to take for the same dose of amprenavir. Although the Committee noted that the use of ritonavir-boosted Telzir had not been studied sufficiently in heavily pretreated patients and that no comparative studies had been carried out in children, it decided that Telzir'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 Telzir?

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

Other information about Telzir:

The European Commission granted a marketing authorisation valid throughout the EU for Telzir on 12 July 2004.

The full EPAR for Telzir 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 Telzir, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2016.