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EPAR summary for the public

Stribild

elvitegravir / cobicistat / emtricitabine / tenofovir disoproxil

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

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

What is Stribild and what is it used for?

Stribild is a medicine that contains the active substances elvitegravir, cobicistat, emtricitabine and tenofovir disoproxil. It is used to treat patients from 12 years of age and weighing at least 35 kg who are infected with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS). It is used only in patients who have not received HIV medicines before or whose disease is not expected to be resistant to any of the antiviral agents in Stribild; it should only be used in patients under 18 years if other HIV medicines not including tenofovir disoproxil cannot be used because of side effects.

How is Stribild used?

Stribild can only be obtained with a prescription and treatment should only be started by a doctor who is experienced in managing HIV infection. Stribild is available as tablets (150 mg elvitegravir/150 mg cobicistat /200 mg emtricitabine/245 mg tenofovir disoproxil). The recommended dose is one tablet a day, taken with food. For further information, see the package leaflet.

How does Stribild work?

Stribild contains four active substances. Elvitegravir is a type of antiviral agent called an ‘integrase inhibitor’. It blocks an HIV-1 enzyme called integrase, which is involved in thevirus’s replication, thereby reducing the virus’s ability to replicate normally and slowing down its spread. Cobicistat

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enhances the effects of elvitegravir, by prolonging the time for which elvitegravir continues to work. Tenofovir disoproxil is a 'prodrug' of tenofovir, meaning that it is converted into the active substance tenofovir in the body. Tenofovir and emtricitabine are closely related types of antiviral agent called reverse transcriptase inhibitors. They block the activity of reverse transcriptase, an enzyme produced by HIV-1 that allows the virus to replicate itself in the body. By blocking reverse transcriptase as well as integrase, Stribild reduces the amount of HIV-1 in the blood and keeps it at a low level.

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

What benefits of Stribild have been shown in studies?

Stribild was investigated in two main studies involving 1,422 adult patients with HIV-1 who had not been treated before, where Stribild was compared with other HIV medicines. The main measure of effectiveness was based on the reduction in viral load (the amount of HIV-1 virus in the blood). Patients whose viral load was reduced to less than 50 HIV-1 RNA copies/ml after 48 weeks of treatment were considered to have responded to treatment.

In the first study, involving 715 patients, Stribild was compared with the combination of ritonavir, atazanavir plus a medicine containing emtricitabine and tenofovir disoproxil (which are also contained in Stribild). After 48 weeks, around 90% of patients treated with Stribild (316 out of 353) responded to treatment compared with around 87% of patients treated with the comparator treatment (308 out of 355).

In the second study, involving 707 patients, Stribild was compared with a medicine containing efavirenz, emtricitabine and tenofovir disoproxil. After 48 weeks, around 88% of patients treated with Stribild (305 out of 348) responded to treatment compared with around 84% of patients treated with the comparator medicine (296 out of 352).

A third study involving 50 adolescents aged 12 to 18 years who had not been previously treated for HIV-1 showed that Stribild was also effective in reducing viral load in this age group; 88% (44 of 50 patients) responded to treatment after 24 weeks, and the response persisted after 48 weeks.

What are the risks associated with Stribild?

The most common side effects with Stribild are nausea (feeling sick) and diarrhoea, which can affect more than 1 in 10 people. In patients taking some of the components of Stribild, certain rare but serious side effects have been seen including lactic acidosis (excess lactic acid in the blood) and severe kidney problems that may also affect bones. For the full list of all side effects reported with Stribild, see the package leaflet.

Stribild must not be used in patients who have previously stopped treatment with tenofovir disoproxil due to kidney toxicity. Stribild must not be used with several other medicines as it may interact with them, thereby reducing the effectiveness of treatment or increasing the risk of side effects. For the full list of restrictions, see the package leaflet.

Why is Stribild approved?

The European Medicines Agency decided that Stribild's benefits are greater than its risks and recommended that it be approved for use in the EU. In particular, the Agency concluded that the benefits of Stribild in reducing HIV viral load had been clearly shown in studies, and noted that it has

the advantage of being taken once per day. The Agency also noted the risk of side effects affecting the kidneys, and recommended that kidney function should be carefully assessed before patients start taking Stribild and should be monitored during treatment.

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

The company that markets Stribild will ensure that all doctors who are expected to prescribe Stribild are provided with educational materials containing important safety information. This will cover information on the risk of kidney disease in adults and adolescents and the measures to reduce this risk, including appropriate screening and monitoring of patients.

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

Other information about Stribild

The European Commission granted a marketing authorisation valid throughout the European Union for Stribild on 24/05/2013

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

This summary was last updated in 10/2017.