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EPAR summary for the public

Aluvia

lopinavir and ritonavir

This document is a summary of the European Public Assessment Report (EPAR) for Aluvia. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion and its recommendations on the conditions of use for Aluvia.

What is Aluvia?

Aluvia is a medicine that contains two active substances, lopinavir and ritonavir. It is available as tablets (pink: 100 mg lopinavir and 25 mg ritonavir; red: 200 mg lopinavir and 50 mg ritonavir).

What is Aluvia used for?

Aluvia is an antiviral medicine. It is used together with other antiviral medicines to treat patients over two years of age who are infected with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS).

Aluvia is identical to a medicine already authorised in the European Union (EU) called Kaletra tablets, except for the appearance of the tablets. It has been developed in the context of co-operation with the World Health Organization (WHO) because it can be used against a WHO target disease (HIV/AIDS). It is to be used exclusively in markets outside the EU.

The medicine can only be obtained with a prescription.

How is Aluvia used?

Treatment with Aluvia should be prescribed by a doctor who has experience in the management of HIV infection.

In adults and adolescents (aged 12 years and over), the recommended dose is two 200/50-mg tablets twice a day. This dose is also suitable for children (aged between two and 12 years) provided that they weigh more than 40 kg and have a body surface area (calculated using the child's height and weight)

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over 1.4 m^2. The dose for smaller children depends on the child's body surface area and the other medicines that the child is taking.

If necessary, adults (aged 18 years and over) can take the full dose of four tablets as a single daily dose if they are infected with HIV that is likely to respond to most medicines in the same class as Aluvia (protease inhibitors). When deciding to use once-daily dosing, the doctor should consider the fact that it might not be as effective as twice-daily dosing at keeping HIV levels low in the long term and may increase the risk of diarrhoea.

Aluvia tablets should be swallowed whole and not chewed, broken or crushed.

How does Aluvia work?

Aluvia contains two active substances, lopinavir and ritonavir. Both substances are protease inhibitors: they block an enzyme called protease that is involved in the reproduction of HIV. When the enzyme is blocked, the virus does not reproduce normally, slowing down the spread of infection. In Aluvia, lopinavir provides the activity and ritonavir is used as a 'booster' that slows down the rate at which lopinavir is broken down by the liver. This increases the levels of lopinavir in the blood, allowing a lower dose of lopinavir to be used for the same antiviral effect. Aluvia does not cure HIV infection or AIDS, but it may delay the damage to the immune system and the development of infections and diseases associated with AIDS.

How has Aluvia been studied?

The changes in the appearance of the tablets have no impact on the product compared with Kaletra. Because Aluvia can be considered identical to Kaletra, and both medicines are used in the same indication and at the same dose, the clinical studies performed with Kaletra also apply to Aluvia.

What benefit has Aluvia shown during the studies?

The benefit associated with Aluvia is identical to that of Kaletra (see below for a link to information on Kaletra).

What is the risk associated with Aluvia?

The risk associated with Aluvia is identical to that of Kaletra (see below for a link to information on Kaletra).

Why has Aluvia been approved?

Aluvia is to be used in the same indication, with the same dose and conditions of use as Kaletra. The only differences from Kaletra relate to the appearance of the tablets. The CHMP agreed that these changes would not have any impact on the benefit/risk ratio. Therefore, the Committee decided that Aluvia's benefits are greater than its risks.

Other information about Aluvia:

The CHMP granted a positive scientific opinion in the context of co-operation with the WHO on 21 September 2006 for Aluvia from Abbott Laboratories Limited.

The full EPAR for Aluvia can be found here. For more information about treatment with Aluvia, read the Package Leaflet (also part of the EPAR).

For reference, the full EPAR for Kaletra can be found here.

This summary was last updated in 08-2010.