EMA/783146/2015
EMEA/H/C/004025

EPAR summary for the public

Lopinavir/Ritonavir Mylan

lopinavir / ritonavir

This is a summary of the European public assessment report (EPAR) for Lopinavir/Ritonavir Mylan. 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 Lopinavir/Ritonavir Mylan.

For practical information about using Lopinavir/Ritonavir Mylan, patients should read the package leaflet or contact their doctor or pharmacist.

What is Lopinavir/Ritonavir Mylan and what is it used for?

Lopinavir/Ritonavir Mylan is used in combination with other 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). Lopinavir/Ritonavir Mylan contains the active substances lopinavir and ritonavir.

Lopinavir/Ritonavir Mylan is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU), called Kaletra. For more information on generic medicines, see the question-and-answer document here.

How is Lopinavir/Ritonavir Mylan used?

Lopinavir/Ritonavir Mylan can only be obtained with a prescription and treatment should be started by a doctor who is experienced in managing HIV infection. It is available as tablets (100 mg lopinavir and 25 mg ritonavir; 200 mg lopinavir and 50 mg ritonavir).

In adults and adolescents (aged 12 years and over), the recommended dose of Lopinavir/Ritonavir Mylan 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 or have a body surface area (calculated using

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

the child's height and weight) 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.

For adults (aged 18 years or over) who are infected with HIV that is likely to respond to medicines in the same class as Lopinavir/Ritonavir Mylan (protease inhibitors) the doctor may prescribe the full daily dose of four 200/50-mg tablets as a single dose. 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. For more information, see the package leaflet.

How does Lopinavir/Ritonavir Mylan work?

The active substances in this medicine, lopinavir and ritonavir, are protease inhibitors: they block an enzyme called protease that is involved in the replication of HIV. When the enzyme is blocked, the virus does not replicate normally, slowing down the spread of infection. In Lopinavir/Ritonavir Mylan, 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.

Lopinavir/Ritonavir Mylan, taken with other HIV medicines, reduces HIV in the blood and keeps the virus at a low level. It does not cure HIV infection, but it can hold off damage to the immune system and avoid the development of infections and diseases associated with AIDS.

How has Lopinavir/Ritonavir Mylan been studied?

Because Lopinavir/Ritonavir Mylan is a generic medicine, studies in people have been limited to tests to determine that it is bioequivalent to the reference medicine, Kaletra. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Lopinavir/Ritonavir Mylan?

Because Lopinavir/Ritonavir Mylan is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Lopinavir/Ritonavir Mylan approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Lopinavir/Ritonavir Mylan has been shown to have comparable quality and to be bioequivalent to Kaletra. Therefore, the CHMP's view was that, as for Kaletra, the benefit outweighs the identified risk. The Committee recommended that Lopinavir/Ritonavir Mylan be approved for use in the EU.

What measures are being taken to ensure the safe and effective use of Lopinavir/Ritonavir Mylan?

A risk management plan has been developed to ensure that Lopinavir/Ritonavir Mylan is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Lopinavir/Ritonavir Mylan, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Lopinavir / Ritonavir Mylan

The European Commission granted a marketing authorisation valid throughout the European Union for Lopinavir/Ritonavir Mylan on 14 January 2016.

The full EPAR and risk management plan summary for Lopinavir/Ritonavir Mylan 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 Lopinavir/Ritonavir Mylan, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 01-2016.