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Ambrisentan Mylan (*ambrisentan*)

An overview of Ambrisentan Mylan and why it is authorised in the EU

What is Ambrisentan Mylan and what is it used for?

Ambrisentan Mylan is a medicine that is used alone or combined with other medicines to treat adults with pulmonary arterial hypertension (PAH).

PAH is abnormally high blood pressure in the arteries of the lungs. Ambrisentan Mylan is used in patients with class II or III disease. The 'class' reflects the severity of the disease: 'class II' involves slight limitation of physical activity and 'class III' involves marked limitation of physical activity. Ambrisentan Mylan is effective in PAH with no identified cause and in PAH caused by connective tissue disease.

Ambrisentan Mylan contains the active substance ambrisentan and is a 'generic medicine'. This means that Ambrisentan Mylan contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Volibris. For more information on generic medicines, see the question-and-answer document here.

How is Ambrisentan Mylan used?

Ambrisentan Mylan can only be obtained with a prescription and treatment must be started by a doctor who has experience in the treatment of PAH.

Ambrisentan Mylan is available as tablets (5 and 10 mg). Treatment is started at a dose of 5 mg daily and the doctor may increase it to 10 mg daily depending on response and any side effects experienced by the patient. The dose is increased to 10 mg daily when the medicine is used with tadalafil (another medicine for PAH). When taken with ciclosporin (a medicine that reduces the activity of the immune system) the dose of Ambrisentan Mylan should be 5 mg daily and the patient should be closely monitored by their doctor.

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

How does Ambrisentan Mylan work?

PAH is a debilitating disease where there is severe narrowing of the blood vessels of the lungs. It causes high blood pressure in the vessels taking blood from the heart to the lungs and reduces the

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flow of blood to the lungs. As a result, the amount of oxygen that can get into the blood in the lungs is reduced, making physical activity more difficult. The active substance in Ambrisentan Mylan, ambrisentan, blocks the receptors (targets) for a hormone called endothelin, which causes blood vessels to become narrow. By blocking the effect of endothelin, Ambrisentan Mylan prevents the vessels becoming too narrow helping to lower the blood pressure and improving symptoms.

How has Ambrisentan Mylan been studied?

Studies on the benefits and risks of the active substance in the authorised use have already been carried out with the reference medicine, Volibris, and do not need to be repeated for Ambrisentan Mylan.

As for every medicine, the company provided studies on the quality of Ambrisentan Mylan. The company also carried out a study that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the benefits and risks of Ambrisentan Mylan?

Because Ambrisentan 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 Ambrisentan Mylan authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Ambrisentan Mylan has been shown to have comparable quality and to be bioequivalent to Volibris. Therefore, the Agency's view was that, as for Volibris, the benefit of Ambrisentan Mylan outweighs the identified risk and it can be authorised for use in the EU.

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

The company that markets Ambrisentan Mylan will provide a patient card containing important information on the medicine's side effects and the need to avoid pregnancy during treatment.

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

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

Other information about Ambrisentan Mylan

Ambrisentan Mylan received a marketing authorisation valid throughout the EU on 20 June 2019.

Further information on Ambrisentan Mylan can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/ambrisentan-mylan. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 06-2019.