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Ambrisentan Viatris[1] (*ambrisentan*)

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

What is Ambrisentan Viatris and what is it used for?

Ambrisentan Viatris 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 Viatris 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 Viatris is effective in PAH with no identified cause and in PAH caused by connective tissue disease.

Ambrisentan Viatris contains the active substance ambrisentan and is a 'generic medicine'. This means that Ambrisentan Viatris 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 Viatris used?

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

Ambrisentan Viatris is available as tablets. It is taken once a day and the dose may be increased depending on the patient's response to treatment and side effects.

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

How does Ambrisentan Viatris 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 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 Viatris,

[1] Previously known as Ambrisentan Mylan.

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ambrisentan, blocks the receptors (targets) for a hormone called endothelin, which causes blood vessels to become narrow. By blocking the effect of endothelin, Ambrisentan Viatris prevents the vessels becoming too narrow helping to lower the blood pressure and improving symptoms.

How has Ambrisentan Viatris 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 Viatris.

As for every medicine, the company provided studies on the quality of Ambrisentan Viatris. 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 Viatris?

Because Ambrisentan Viatris 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 Viatris authorised in the EU?

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

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Ambrisentan Viatris have been included in the summary of product characteristics and the package leaflet. Any additional measures in place for Volibris, such as a patient card with key safety information, also apply to Ambrisentan Viatris where appropriate.

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

Other information about Ambrisentan Viatris

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

The name of the medicine was changed to Ambrisentan Viatris on 15 October 2024.

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

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