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EPAR summary for the public

Amlodipine/Valsartan Mylan

amlodipine / valsartan

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

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

What is Amlodipine/Valsartan Mylan and what is it used for?

Amlodipine/Valsartan Mylan is a medicine used in patients who have essential hypertension (high blood pressure) that is not adequately controlled on either amlodipine or valsartan taken alone. 'Essential' means that the hypertension has no obvious cause.

Amlodipine/Valsartan Mylan contains two active substances, amlodipine and valsartan. It is a 'generic medicine'. This means that Amlodipine/Valsartan Mylan is similar to a 'reference medicine' already authorised in the European Union (EU) called Exforge. For more information on generic medicines, see the question-and-answer document here.

How is Amlodipine/Valsartan Mylan used?

Amlodipine/Valsartan Mylan is available as tablets (5 mg amlodipine and 80 mg valsartan; 5 mg amlodipine and 160 mg valsartan; 10 mg amlodipine and 160 mg valsartan). One tablet is taken daily by mouth with water. It is recommended that the patient takes amlodipine and valsartan as separate tablets or capsules before switching to the combination tablet. The strength of the tablet to be used depends on the doses of amlodipine or valsartan that the patient was taking before.

The medicine can only be obtained with a prescription.

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

How does Amlodipine/Valsartan Mylan work?

Amlodipine/Valsartan Mylan contains two active substances, amlodipine and valsartan. Both are anti–hypertensive medicines that have been available separately in the European Union (EU) since the mid-1990s. They work in similar ways to reduce blood pressure by allowing the blood vessels to relax. By lowering the blood pressure, the risks associated with high blood pressure, such as having a stroke, are reduced.

Amlodipine is a calcium channel blocker. It blocks special channels on the surface of cells through which calcium normally enters the cells. When calcium enters the cells in the muscles of blood vessel walls, this causes contraction. By reducing the flow of calcium into the cells, amlodipine prevents the cells from contracting and this helps the blood vessels to relax.

Valsartan is an 'angiotensin II receptor antagonist', which means that it blocks the action of a hormone in the body called angiotensin II. Angiotensin II is a powerful vasoconstrictor (a substance that narrows blood vessels). By blocking the receptors to which angiotensin II normally attaches, valsartan stops the hormone having an effect, allowing the blood vessels to widen.

How has Amlodipine/Valsartan Mylan been studied?

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

What are the benefits and risks of Amlodipine/Valsartan Mylan?

Because Amlodipine/Valsartan 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 Amlodipine/Valsartan Mylan approved?

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

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

A risk management plan has been developed to ensure that Amlodipine/Valsartan 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 Amlodipine/Valsartan Mylan, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Amlodipine/Valsartan Mylan

The European Commission granted a marketing authorisation valid throughout the European Union for Amlodipine/Valsartan Mylan on 22 March 2016.

The full EPAR for Amlodipine/Valsartan 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 Amlodipine/Valsartan 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 03-2016.