LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Amlodipin Valsartan Actavis
(amlodipine besilate, valsartan)

SE/H/1535/01-03/DC

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Amlodipin Valsartan Actavis

(amlodipine besilate, valsartan)

Film-coated tablet, 5 mg/80 mg, 5 mg/160 mg, 10 mg/160 mg

This is a summary of the public assessment report (PAR) for Amlodipin Valsartan Actavis. It explains how Amlodipin Valsartan Actavis was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Amlodipin Valsartan Actavis.

For practical information about using Amlodipin Valsartan Actavis, patients should read the package leaflet or contact their doctor or pharmacist.

What is Amlodipin Valsartan Actavis and what is it used for?

Amlodipin Valsartan Actavis is a 'generic medicine'. This means that Amlodipin Valsartan Actavis is similar to a 'reference medicine' already authorised in the European Union (EU) called Exforge.

Amlodipin Valsartan Actavis is used to treat high blood pressure in adults whose blood pressure is not controlled enough with either amlodipine or valsartan on its own.

How does Amlodipin Valsartan Actavis work?

Amlodipin Valsartan Actavis tablets contain two substances called amlodipine and valsartan. Both of these substances help to control high blood pressure.

- Amlodipine belongs to a group of substances called "calcium channel blockers". Amlodipine stops calcium from moving into the blood vessel wall which stops the blood vessels from tightening.
- Valsartan belongs to a group of substances called "angiotensin-II receptor antagonists".

Angiotensin II is produced by the body and makes the blood vessels tighten, thus increasing the blood pressure. Valsartan works by blocking the effect of angiotensin II.
This means that both of these substances help to stop the blood vessels tightening. As a result, the blood vessels relax and blood pressure is lowered.

How is Amlodipin Valsartan Actavis used?

The pharmaceutical form of Amlodipin Valsartan Actavis is film-coated tablet for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Amlodipin Valsartan Actavis have been shown in studies?

Because Amlodipin Valsartan Actavis is a generic medicine, studies in patients 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 possible side effects of Amlodipin Valsartan Actavis?

Because Amlodipin Valsartan Actavis is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Amlodipin Valsartan Actavis approved?

It was concluded that, in accordance with EU requirements, Amlodipin Valsartan Actavis has been shown to have comparable quality and to be bioequivalent to the reference medicine Exforge. Therefore, the Medical Products Agency in Sweden decided that, as for Exforge, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Amlodipin Valsartan Actavis?

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

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Amlodipin Valsartan Actavis

The marketing authorisation for Amlodipin Valsartan Actavis was granted on 2016-11-25 in Sweden.

The full PAR for Amlodipin Valsartan Actavis can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Amlodipin Valsartan Actavis, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2016-12.