LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Amlodipine/Valsartan Denk

(amlodipine besilate, valsartan)

SE/H/1615/01-03/DC

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Amlodipine/Valsartan Denk

(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 Amlodipine/Valsartan Denk. It explains how Amlodipine/Valsartan Denk 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 Amlodipine/Valsartan Denk.

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

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

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

Amlodipine/Valsartan Denk 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 Amlodipine/Valsartan Denk work?

Amlodipine/Valsartan Denk 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 Amlodipine/Valsartan Denk used?

The pharmaceutical form of Amlodipine/Valsartan Denk 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 Amlodipine/Valsartan Denk have been shown in studies?

Because Amlodipine/Valsartan Denk 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 Amlodipine/Valsartan Denk?

Because Amlodipine/Valsartan Denk 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 Amlodipine/Valsartan Denk approved?

It was concluded that, in accordance with EU requirements, Amlodipine/Valsartan Denk 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 Amlodipine/Valsartan Denk?

A risk management plan has been developed to ensure that Amlodipine/Valsartan Denk 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 Denk, 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 Amlodipine/Valsartan Denk

The marketing authorisation for Amlodipine/Valsartan Denk was granted on 2017-01-27 in Sweden.

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

This summary was last updated in 2017-02.