LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Amlodipin Accord
(amlodipine)

SE/H/842/01-02/E01

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Summary Public Assessment Report

Amlodipin Accord

(amlodipine)

Tablet 5 mg, 10 mg

This is a summary of the public assessment report (PAR) for Amlodipin Accord. It explains how Amlodipin Accord 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 Accord.

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

What is Amlodipin Accord and what is it used for?

Amlodipin Accord is a ‘generic medicine’. This means that Amlodipin Accord is similar to a ‘reference medicine’ already authorised in the European Union (EU) called Norvasc.

Amlodipin Accord is used to treat high blood pressure (hypertension) or a certain type of chest pain called angina, a rare form of which is Prinzmetal’s or variant angina.

How does Amlodipin Accord work?

Amlodipin Accord contains the active substance amlodipine which belongs to a group of medicines called calcium antagonists.

In patients with high blood pressure this medicine works by relaxing blood vessels, so that blood passes through them more easily. In patients with angina, Amlodipin Accord works by improving blood supply to the heart muscle which then receives more oxygen and as a result chest pain is prevented. This medicine does not provide immediate relief of chest pain from angina.

How is Amlodipin Accord used?

The pharmaceutical form of Amlodipin Accord is 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 Accord have been shown in studies?

Because Amlodipin Accord is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Norvasc. 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 Accord?

Because Amlodipin Accord 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 Accord approved?

It was concluded that, in accordance with EU requirements, Amlodipin Accord has been shown to have comparable quality and to be bioequivalent to the reference medicine Norvasc. Therefore, the Medical Products Agency in Sweden decided that, as for Norvasc, 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 Accord?

A risk management plan has been developed to ensure that Amlodipin Accord 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 Accord, 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 Accord

The marketing authorisation for Amlodipin Accord was granted on 2008-10-10 in Sweden.

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

This summary was last updated in 2017-03.