

Summary Public Assessment Report

Amlodipin Orion (amlodipine besilate)

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(amlodipine besilate)

Tablet, 5mg and 10 mg

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

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

What is Amlodipin Orion and what is it used for?

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

Amlodipin Orion 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 Orion work?

Amlodipin Orion 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 Orion 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 Orion used?

The pharmaceutical form of Amlodipin Orion 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 Orion have been shown in studies?

Because Amlodipin Orion 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 Orion?

Because Amlodipin Orion 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 Orion approved?

It was concluded that, in accordance with EU requirements, Amlodipin Orion 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 Orion?

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

The marketing authorisation for Amlodipin Orion was granted on 2017-11-28 in Sweden.

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

This summary was last updated in 2017-11.