

# **Summary Public Assessment Report**

## **Amlodipin/Valsartan Teva (amlodipine besilate, valsartan)**

**SE/H/2143/01-03/DC**

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Amlodipin/Valsartan Teva  
amlodipine, 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 Teva. It explains how Amlodipin/Valsartan Teva 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 Teva.

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

## What is Amlodipin/Valsartan Teva and what is it used for?

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

Amlodipin/Valsartan Teva 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 Teva work?

Amlodipin/Valsartan Teva 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 Teva used?

The pharmaceutical form of Amlodipin/Valsartan Teva 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 in Sweden.

## What benefits of Amlodipin/Valsartan Teva have been shown in studies?

Because Amlodipin/Valsartan Teva is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Exforge.

### **What are the possible side effects from Amlodipin/Valsartan Teva?**

Because Amlodipin/Valsartan Teva is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

### **Why is Amlodipin/Valsartan Teva approved?**

It was concluded that, in accordance with EU requirements, Amlodipin/Valsartan Teva has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine Exforge. Therefore, the Swedish Medical Products Agency 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 Teva?**

A risk management plan has been developed to ensure that Amlodipin/Valsartan Teva 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 Teva, 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 Teva**

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

This summary was last updated in 2022-09-27.