LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Amlodipin/Valsartan/Hydroklortiazid Teva

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Summary Public Assessment Report

Amlodipin/Valsartan/Hydroklortiazid Teva
(amlodipine besilate, valsartan, hydrochlorothiazide)

Film-coated tablet, 5 mg/160 mg/12,5 mg, 10 mg/320 mg/25 mg

This is a summary of the public assessment report (PAR) for Amlodipin/Valsartan/Hydroklortiazid Teva. It explains how Amlodipin/Valsartan/Hydroklortiazid 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/Hydroklortiazid Teva.

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

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

Amlodipin/Valsartan/Hydroklortiazid Teva is a 'generic medicine'. This means that Amlodipin/Valsartan/Hydroklortiazid Teva is similar to a 'reference medicine' already authorised in the European Union (EU) called Exforge HCT.
Amlodipin/Valsartan/Hydroklortiazid Teva is used to treat high blood pressure in adult patients whose blood pressure is already controlled while taking amlodipine, valsartan and hydrochlorothiazide and who may benefit from taking one tablet containing all three substances.

How does Amlodipin/Valsartan/Hydroklortiazid Teva work?

Amlodipin/Valsartan/Hydroklortiazid Teva tablets contain three substances called amlodipine, valsartan and hydrochlorothiazide. All 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.
- Hydrochlorothiazide belongs to a group of substances called "thiazide diuretics". Hydrochlorothiazide increases urine output, which also lowers blood pressure.

As a result of all three mechanisms, the blood vessels relax and blood pressure is lowered.

How is Amlodipin/Valsartan/Hydroklortiazid Teva used?

The pharmaceutical form of Amlodipin/Valsartan/Hydroklortiazid 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/Hydroklortiazid Teva have been shown in studies?

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

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/Hydroklortiazid Teva?

Because Amlodipin/Valsartan/Hydroklortiazid 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 restrictions, see the package leaflet.

Why is Amlodipin/Valsartan/Hydroklortiazid Teva approved?

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

Amlodipin/Valsartan/Hydroklortiazid Teva has been authorised with the condition to perform further studies and/or to provide additional measures to minimise the risk. See section below "What measures are being taken to ensure the safe and effective use of Amlodipin/Valsartan/Hydroklortiazid Teva?"

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

A risk management plan has been developed to ensure that Amlodipin/Valsartan/Hydroklortiazid 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/Hydroklortiazid 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.

In accordance with a European referral procedure (EMEA/H/A-31/1471) there is an obligation that the company reviews their manufacturing processes in order not to produce nitrosamine impurities. This is expected to be completed by 2021-04-02.

Other information about Amlodipin/Valsartan/Hydroklortiazid Teva

The full PAR for Amlodipin/Valsartan/Hydroklortiazid Teva can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with

Amlodipin/Valsartan/Hydroklortiazid Teva, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2020-08.