LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Valtensam Comp

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Summary Public Assessment Report

Valtensam Comp
(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 Valtensam Comp. It explains how Valtensam Comp 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 Valtensam Comp.

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

What is Valtensam Comp and what is it used for?

Valtensam Comp is a 'generic medicine'. This means that Valtensam Comp is similar to a 'reference medicine' already authorised in the European Union (EU) called Exforge HCT. Valtensam Comp 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 Valtensam Comp work?

Valtensam Comp 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 Valtensam Comp used?

The pharmaceutical form of Valtensam Comp 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 Valtensam Comp have been shown in studies?

Because Valtensam Comp 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 Valtensam Comp?

Because Valtensam Comp 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 Valtensam Comp approved?

It was concluded that, in accordance with EU requirements, Valtensam Comp 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.

Valtensam Comp 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 Valtensam Comp?”

What measures are being taken to ensure the safe and effective use of Valtensam Comp?

A risk management plan has been developed to ensure that Valtensam Comp 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 Valtensam Comp, 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 Valtensam Comp

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

This summary was last updated in 2020-08.