LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Bevacomb

(amlodipine besilate, valsartan)

SE/H/1521/01-03/DC

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@mpa.se

Summary Public Assessment Report

Bevacomb

(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 Bevacomb. It explains how Bevacomb 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 Bevacomb.

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

What is Bevacomb and what is it used for?

Bevacomb is a 'generic medicine'. This means that Bevacomb is similar to a 'reference medicine' already authorised in the European Union (EU) called Exforge.

Bevacomb 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 Bevacomb work?

Bevacomb 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 Bevacomb used?

The pharmaceutical form of Bevacomb 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.

What benefits of Bevacomb have been shown in studies?

Because Bevacomb is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Exforge. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Bevacomb?

Because Bevacomb 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 Bevacomb approved?

It was concluded that, in accordance with EU requirements, Bevacomb has been shown to have comparable quality and to be bioequivalent to the reference medicine Exforge. Therefore, the Medical Products Agency in Sweden 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 Bevacomb?

A risk management plan has been developed to ensure that Bevacomb 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 Bevacomb, 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 Bevacomb

The marketing authorisation for Bevacomb was granted on 2016-11-25 in Sweden.

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

This summary was last updated in 2016-12.