LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Valsartan Jubilant
(valsartan)

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Summary Public Assessment Report

Valsartan Jubilant

(valsartan)

Film-coated tablet; 320 mg

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

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

What is Valsartan Jubilant and what is it used for?
Valsartan Jubilant is a 'generic medicine'. This means that Valsartan Jubilant is similar to a 'reference medicine' already authorised in the European Union (EU) called Diovan.

Valsartan Jubilant is used to treat high blood pressure in adults and in children and adolescents 6 to 18 years of age.

How does Valsartan Jubilant work?
Valsartan Jubilant belongs to a class of medicines known as angiotensin II receptor antagonist, which help to control high blood pressure. Angiotensin II is a substance in the body that causes vessels to tighten, thus causing your blood pressure to increase. Valsartan Jubilant works by blocking the effect of angiotensin II. As a result, blood vessels relax and blood pressure is lowered.

How is Valsartan Jubilant used?
The pharmaceutical form of Valsartan Jubilant 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 Valsartan Jubilant have been shown in studies?
Because Valsartan Jubilant is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Diovan. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Valsartan Jubilant?
Because Valsartan Jubilant 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 Valsartan Jubilant approved?
It was concluded that, in accordance with EU requirements, Valsartan Jubilant has been shown to have comparable quality and to be bioequivalent to the reference medicine Diovan. Therefore, the Medical Products Agency in Sweden decided that, as for Diovan, 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 Valsartan Jubilant?
A risk management plan has been developed to ensure that Valsartan Jubilant 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 Valsartan Jubilant, 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 Valsartan Jubilant
The marketing authorisation for Valsartan Jubilant was granted on 2014-10-23 in Sweden.

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

This summary was last updated in 2014-10-23.