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Summary Public Assessment Report

Generics

Casaro 8 mg, 16 mg, 32 mg
Candesartan cilexetil

SK/H/0266/001-003/DC

Date: May 2022

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

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

What is Casaro and what is it used for?

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

Casaro is used in the treatment of

- high blood pressure (hypertension) in adult patients and in children and adolescents aged 6 to 18 years,
- heart failure in adult patients with reduced heart muscle function when Angiotensin Converting Enzyme (ACE) inhibitors cannot be used or in addition to ACE-inhibitors when symptoms persist despite treatment and mineralocorticoid receptor antagonists (MRA) cannot be used (ACE-inhibitors and MRAs are medicines used to treat heart failure).

How does Casaro work?

The active ingredient is candesartan cilexetil. This belongs to a group of medicines called angiotensin II receptor antagonists. It works by making your blood vessels relax and widen. This helps to lower your blood pressure. It also makes it easier for your heart to pump blood to all parts of your body.

How is Casaro used?

The pharmaceutical form of Casaro is tablet and the route of administration is oral.

Please read section 3 of the PL 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 Casaro have been shown in studies?

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

What are the possible side effects of Casaro?

Because Casaro 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 Casaro approved?

It was concluded that, in accordance with EU requirements, Casaro has been shown to have comparable quality and to be bioequivalent to Atacand. Therefore, the State Institute for Drug Control decided that, as for Atacand the benefits are greater than its risk and recommended that it can be approved for use.

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

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

The marketing authorisation for Casaro was granted on 13 July 2022.

The full PAR for Casaro can be found on the website https://www.sukl.sk/. For more information about treatment with Casaro, read the package leaflet (*link*) or contact your doctor or pharmacist.

This summary was last updated in May 2022.