

Summary Public Assessment Report

Ramiliv
(ramipril)

SE/H/2069/01-03/DC

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ramipril

Tablet, 2,5 mg, 5 mg, 10 mg

This is a summary of the public assessment report (PAR) for Ramiliv. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Ramiliv and what is it used for?

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Triatec.

Ramiliv can be used:

- To treat high blood pressure (hypertension),
- To reduce the risk of having a heart attack or stroke,
- To reduce the risk or delay the worsening of kidney problems (whether or not the patient has diabetes),
- To treat the heart when it cannot pump enough blood to the rest of the body (heart failure),
- As treatment following heart attack (myocardial infarction) complicated with heart failure.

How does Ramiliv work?

Ramiliv contains a medicine called ramipril. This belongs to a group of medicines called ACE inhibitors (Angiotensin Converting Enzyme Inhibitors).

Ramiliv works by:

- Decreasing the body's production of substances that could raise the blood pressure,
- Making the blood vessels relax and widen,
- Making it easier for the heart to pump blood around the body.

How is Ramiliv used?

The pharmaceutical form is 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 Ramiliv have been shown in studies?

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

What are the possible side effects from Ramiliv?

Because the product 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 side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Ramiliv approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Triatec, 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 Ramiliv?

A risk management plan has been developed to ensure that the product 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, 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 Ramiliv

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

This summary was last updated in 2024-03.