LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Ramipril/Amlodipine Zentiva (ramipril/amlodipine)

SE/H/1339/01-05/DC

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Capsules, hard; 2, 5 mg/5 mg, 5 mg/5 mg, 10 mg/5 mg, 5 mg/10 mg and 10 mg/10 mg

This is a summary of the public assessment report (PAR) for Ramipril/Amlodipine Zentiva. It explains how Ramipril/Amlodipine Zentiva 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 Ramipril/Amlodipine Zentiva.

For practical information about using Ramipril/Amlodipine Zentiva, patients should read the package leaflet or contact their doctor or pharmacist.

What is Ramipril/Amlodipine Zentiva and what is it used for?

Ramipril/Amlodipine Zentiva is used to treat hypertension (high blood pressure), in patients whose blood pressure is adequately controlled with amlodipine and ramipril given concurrently at the same dose level as in Ramipril/Amlodipine Zentiva, but as a separate medicines.

How does Ramipril/Amlodipine Zentiva work?

Ramipril/Amlodipine Zentiva contains two active substances: ramipril and amlodipine.

Ramipril works by:
- Decreasing your body's production of substances that could raise your blood pressure
- Making your blood vessels relax and widen
- Making it easier for your heart to pump blood around your body

Amlodipine works by:
- Relaxing and widening blood vessels, so that blood passes through them more easily.

How is Ramipril/Amlodipine Zentiva used?

The pharmaceutical form of Ramipril/Amlodipine Zentiva is hard caspules 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 Ramipril/Amlodipine Zentiva have been shown in studies?

Because Ramipril/Amlodipine Zentiva is used for patients whose blood pressure is adequately controlled with amlodipine and ramipril given concurrently but as a separate medicines, studies in patients have been limited to tests to determine that Ramipril/Amlodipine Zentiva is bioequivalent to the use of the combination of separate medicinies containing amlodipine and

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ramipril respectively. The medicines are bioequivalent when they produce the same levels of the active substances in the body.

What are the possible side effects of Ramipril/Amlodipine Zentiva?

For the full list of all side effects reported with Ramipril/Amlodipine Zentiva, see section 4 of the package leaflet.

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

Why is Ramipril/Amlodipine Zentiva approved?

It was concluded that Ramipril/Amlodipine Zentiva has been shown to be bioequivalent to the use of the combination of separate medicinies containing amlodipine and ramipril respectively. Therefore, the Medical Products Agency in Sweden decided that the benefits for Ramipril/Amlodipine Zentiva 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 Ramipril/Amlodipine Zentiva?

A risk management plan has been developed to ensure that Ramipril/Amlodipine Zentiva 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 Ramipril/Amlodipine Zentiva, 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 Ramipril/Amlodipine Zentiva

The marketing authorisation for Ramipril/Amlodipine Zentiva was granted on 2014-08-28 in Sweden.

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

This summary was last updated in 2014-08-28.

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