LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Torasemid Zentiva
(torasemide (anhydrous))

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Summary Public Assessment Report

Torasemid Zentiva
torasemide (anhydrous)

Tablet, 2,5 mg, 5 mg, 10 mg, 20 mg

This is a summary of the public assessment report (PAR) for Torasemid Zentiva. 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 Torasemid Zentiva and what is it used for?

The strengths 2,5 mg, 5 mg and 10 mg of this product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Torem.

The strength 20 mg of this product is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance, but is available in a different strength.

The reference medicine for the product is Torem.

The company has provided additional own data to demonstrate the safety and efficacy of the product regarding this difference from the reference medicine.

The product is used to treat swelling caused by accumulated fluid in body tissues (oedema).
In addition, Torasemid Zentiva 2.5 mg and 5 mg tablets are used to treat high blood pressure.

How does Torasemid Zentiva work?

This medicine is a diuretic (increase passing of urine), but with the dosage that is relevant for blood pressure treatment and it has a weak diuretic effect.

How is Torasemid Zentiva used?

The pharmaceutical form is tablet 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 Torasemid Zentiva 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, Torem. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Torasemid Zentiva?

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 Torasemid Zentiva 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 Torem, 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 Torasemid Zentiva?

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 Torasemid Zentiva

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

This summary was last updated in 2023-11.