Summary Public Assessment Report

non-generics

Betaserc 24 mg orodispersible tablet (Betahistine dihydrochloride)

FI/H/827/01/DC

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non-generics

Betaserc
betahistine dihydrochloride, orodispersible tablet, 24 mg

This is a summary of the public assessment report (PAR) for Betaserc 24 mg orodispersible tablets (ODT). It explains how Betaserc 24 mg ODT 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 Betaserc 24 mg ODT.

For practical information about using Betaserc 24 mg ODT, patients should read the package leaflet or contact their doctor or pharmacist.

What is Betaserc 24 mg ODT and what is it used for?

Betaserc 24 mg ODT is used in adults for symptomatic treatment of Ménière's syndrome and vestibular vertigo.

The signs of Ménière's disease include feeling dizzy (vertigo) and feeling or being sick (nausea or vomiting), ringing in the ears (tinnitus), and hearing loss or hearing difficulty. “Feeling dizzy” is caused when the part of the inner ear which controls balance is not working properly (this is also called vestibular vertigo).

How does Betaserc 24 mg ODT work?

Betaserc 24 mg ODT works by improving the blood flow in the inner ear. The inner ear is one of the organs responsible for sense of balance.

How is Betaserc 24 mg ODT used?

The pharmaceutical form of this medicinal product is orodispersible tablet and the route of administration is peroral.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The recommended dose is one tablet twice a day. Tablets should be taken evenly over the day and at the same time each day.

The orodispersible tablet is placed on the tongue and allowed to disintegrate before swallowing it with or without water. Betaserc 24 mg ODT can be taken with or without food but taking the tablet with food can help reduce stomach problems.

The medicine can only be obtained with a prescription.

What benefits of Betaserc 24 mg ODT have been shown in studies?

The company provided its own data on efficacy and safety of betahistine (that is, the active substance of Betaserc 24 mg ODT). In these studies, betahistine was more effective than placebo (dummy treatment) at improving symptoms of Ménière's syndrome and vestibular vertigo in adult patients.

What are the possible side effects from Betaserc 24 mg ODT?

The most common side effects with Betaserc 24 mg ODT (which may affect up to 1 in 10 people) are feeling sick (nausea), indigestion (dyspepsia), and headache. For the full list of all side effects reported with Betaserc 24 mg ODT, see section 4 of the package leaflet.

Betaserc 24 mg ODT should not be taken if the patient has an adrenal gland tumour (also called “phaeochromocytoma”). Care should be taken before administering Betaserc 24 mg ODT if the patient has asthma or has ever had a stomach ulcer. For the full list of restrictions, see the package leaflet.

Why is Betaserc 24 mg ODT approved?

Finnish Medicines Agency decided in agreement with all the participating Member States that Betaserc 24 mg ODT’s benefits are greater than its risks and recommended that it be approved for use.

A risk management plan has been developed to ensure that Betaserc 24 mg ODT is used as safely as possible. Based on this plan, safety information has generally been included in the summary of product characteristics and the package leaflet for Betaserc 24 mg ODT, 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 Betaserc 24 mg ODT

The marketing authorisation for Betaserc 24 mg ODT was granted on 17.02.2015.

The full PAR for Betaserc 24 mg ODT can be found on the website http://mri.medagencies.org/Human/Product/Details/42898.

For more information about treatment with Betaserc 24 mg ODT, read the package leaflet http://mri.medagencies.org/download/FI_H_0827_001_FinalPL.pdf or contact your doctor or pharmacist.

This summary was last updated in 05-2015.