LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Azalonum
(cinnarizine/dimenhydrinate)

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Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@mpa.se

Azalonum (cinnarizine/dimenhydrinate)

Tablet; 20 mg/40 mg

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

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

What is Azalonum and what is it used for?

Azalonum is a 'generic medicine'. This means that Azalonum is similar to a 'reference medicine' already authorised in the European Union (EU) called Arlevert.
Azalonum is used for the treatment of various kinds of vertigo in adults. Vertigo can have a number of different causes.

How does Azalonum work?

Azalonum contains two active ingredients. One is cinnarizine and one is dimenhydrinate. The two substances belong to different groups of medicines. Cinnarizine is part of a group called calcium antagonists. Dimenhydrinate belongs to a group called antihistamines.

Both substances work by reducing symptoms of vertigo (a feeling of dizziness or 'spinning') and nausea (feeling sick). When these two substances are used together they are more effective than when each one is used on its own.

How is Azalonum used?

The pharmaceutical form of Azalonum 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.

What benefits of Azalonum have been shown in studies?

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

What are the possible side effects of Azalonum?

Because Azalonum 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 Azalonum approved?

It was concluded that, in accordance with EU requirements, Azalonum has been shown to have comparable quality and to be bioequivalent to the reference medicine Arlevert. Therefore, the Medical Products Agency in Sweden decided that, as for Arlevert, 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 Azalonum?

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

The marketing authorisation for Azalonum was granted on 2019-11-05 in Sweden.

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

This summary was last updated in 2019-11.