LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Dotavision
(gadoteric acid, gadolinium oxide, tetraxetan)

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Solution for injection, 0,5 mmol/ml

This is a summary of the public assessment report (PAR) for Dotavision. 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 Dotavision 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 Dotarem.

The product is a contrast agent that contains gadoteric acid. It is for diagnostic use only. It is used to enhance the contrast of the images obtained in examinations with Magnetic Resonance Imaging (MRI). This contrast enhancement improves the visualisation and delineation in:

How does Dotavision work?
Dotavision is a paramagnetic contrast agent for magnetic resonance imaging. The contrast-enhancing effect is mediated by gadoteric acid which is a ionic gadolinium complex composed out of Gadolinium oxide and tetraxetan, and present as meglumine salt.

How is Dotavision used?
The pharmaceutical form is solution for injection.

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 Dotavision have been shown in studies?
No additional studies were needed as the product is a generic medicine that is given by infusion/intravenous injection and contains the same active substance as the reference medicine, Dotarem.

What are the possible side effects from Dotavision?
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 Dotavision approved?
It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be similar to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Dotarem, 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 Dotavision?
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 Dotavision
The full PAR for Dotavision can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Dotavision , please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2024-12.