LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Clariscan
(gadoteric acid)

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Summary Public Assessment Report

Clariscan

gadoteric acid

Solution for injection and Solution for injection in prefilled syringe 0,5 mmol/ml (equivalent to 279,3 mg/ml).

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

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

What is Clariscan and what is it used for?

Clariscan is a 'generic medicine'. This means that Clariscan is similar to a 'reference medicine' already authorised in the European Union (EU) called Dotarem.

Clariscan contains the active substance gadoteric acid. It belongs to a group called "contrast agents" used for magnetic resonance imaging" (MRI).

Clariscan is used to enhance the contrast of the images obtained during MRI examinations.

In adults and in children and adolescents 0-18 years old:

- MRI of the CNS including of defects (lesions) in brain, spine, and surrounding tissues

In adults and in children and adolescents 6 months – 18 years old:

- Whole body MRI including defects (lesions)

In adults only:

- MR angiography including defects (lesions) or narrowing (stenosis) in arteries, except in coronary arteries.

This medicine is for diagnostic use only

How does Clariscan work?

Clariscan makes the pictures on an MRI scanner easier to see. It does this by increasing the contrast between the part of the body being looked at and the rest of the body. This allows doctors or radiologists to see different areas of the body better.

How is Clariscan used?

The pharmaceutical form of Clariscan is solution for injection and solution for injection in prefilled syringe.

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 Clariscan have been shown in studies?

No additional studies were needed as Clariscan 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 of Clariscan?

Because Clariscan 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 restrictions, see the package leaflet.

Why is Clariscan approved?

It was concluded that, in accordance with EU requirements, Clariscan has been shown to have comparable quality and to be similar to the reference medicine Dotarem. Therefore, the Medical Products Agency in Sweden 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 Clariscan?

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

The marketing authorisation for Clariscan was granted on 2017-02-20 in Sweden.

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

This summary was last updated in 2017-03.