

Summary Public Assessment Report

Primovist (disodium gadoxetate, gadoxetic acid)

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disodium gadoxetate, gadoxetic acid

Solution for injection in pre-filled syringe, 0,25 mmol/ml
Solution for injection, 0,25 mmol/ml

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

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

What is Primovist and what is it used for?

Primovist is a contrast medium for magnetic resonance imaging (MRI) of the liver. It is used to help detect and diagnose changes that may be found in the liver. Abnormal signs within the liver can be better evaluated as to number, size, and distribution. Primovist can also help the doctor determine the nature of any abnormalities, thereby increasing the confidence in the diagnosis.

How does Primovist work?

Primovist is a medicine for diagnostic use only. It is a contrast medium for magnetic resonance imaging (MRI) of the liver. MRI is a form of medical diagnostic imaging that forms pictures after water molecules have been detected in normal and abnormal tissues. This is done using a complex system of magnets and radio waves.

How is Primovist used?

The pharmaceutical form of Primovist is solution for injection in pre-filled syringe and 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 Primovist have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that Primovist is effective in the detection of focal liver lesions and to provide information on the character of lesions in T1-weighted magnetic resonance imaging (MRI).

What are the possible side effects of Primovist?

For the full list of all side effects reported with Primovist, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Primovist approved?

It was noted that an improvement in correctly detected liver lesions as well as a higher proportion of correctly characterised lesions in combined pre-and post-contrast MRI compared to pre-contrast MRI has been shown for Primovist in the indication to detect focal liver lesions and to provide information on the character of lesions in T1-weighted magnetic resonance imaging (MRI).

Therefore, the Medical Products Agency in Sweden decided that Primovist's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Primovist?

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

The full PAR for Primovist can be found on the following website:

<http://mri.medagencies.org/Human/>. For more information about treatment with Primovist, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2021-04.