LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Resotran
(ferucarbotran)

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Suspension for injection, 540 mg/ml

This is a summary of the public assessment report (PAR) for Resotran. 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 Resotran and what is it used for?

The product is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance, but is available as suspension for injection instead of as solution for injection in prefilled syringe.

The reference medicine for the product is Resovist.

The product contains the active substance ferucarbotran. It is a contrast medium for magnetic resonance imaging (MRI) of the liver in adult patients. It is used when examination without contrast media has given uncertain findings.

This medicine is for diagnostic use only.

How does Resotran work?

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 radiowaves.

How is Resotran used?

The pharmaceutical form is suspension 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 Resotran have been shown in studies?

Because the product is a hybrid application and is considered to be similar to the reference product Resovist, the benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects from Resotran?

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 Resotran 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 Resovist. Therefore, the Swedish Medical Products Agency decided that, as for Resovist, 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 Resotran?

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 Resotran

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

This summary was last updated in 2022-11-03.