Package leaflet: Information for the user

Resotran 540 mg/ml suspension for injection

ferucarbotran

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [invented name] is and what it is used for

[invented name] 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.

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.

2. What you need to know before you are given [invented name]

You must not receive [invented name]
- if you are allergic to ferucarbotran, dextran or any of the other ingredients of this medicine (listed in section 6).
- If you have experienced serious allergic reactions to other injectable iron containing medicines.

Warnings and precautions
Talk to your doctor or nurse before receiving [invented name]:
- if you had an allergic reaction to contrast media
- if you have or have had asthma or other allergies
- if you have any condition which can give you too much iron in your body (e.g. haemosiderosis or diseases with frequent blood transfusions or chronic iron replacements).

Children and adolescents
[invented name] should not be given to children and adolescents younger than 18 years since it is unknown if and how the medicine works in these patients.

Other medicines and [invented name]
Tell your doctor if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you recieve this medicine.

Pregnagncy
The effects of the medicine during pregnancy is unknown, but iron containing medicine may cause a transient changed heart rhythm in the foetus. [invented name] should, therefore, not be given during pregnancy unless clearly necessary. If the medicine is used in a pregnant woman, the unborn child should be carefully monitored during the treatment of the mother.

Breast-feeding
It is not known if this medicine enters breast milk. [invented name] should, therefore, only be used after special consideration. If you are breast-feeding and are in need of the medicine, you should stop the breast feeding for a few days following the treatment. The breast milk from this stop should be discarded for the safety of your child.

Driving and using machines
The effects of [invented name] on the abiltiy to drive has not been investigated. If you feel unwell after examination, you should not drive or use machines, because nausea may incidentally occur.

[invented name] contains sodium.
This medicinal product contains less than 1 mmol sodium (23 mg) per 1.4 ml, i.e. essentially ´sodium-free`.

3. How [invented name] is given

You will recive the medicine in an environment where the healthcare staff is experienced to this type of treatments and they are aware of the risk of an allergic reaction following the injection, and how to treat you it if needed.

Contrast media can also cause nausea and vomiting. You should therefore not eat anything for 2 hours before the examination.

[invented name] is injected into a vein directly before your MRI examination. The dose depends on your body weight and the doctor will give you the right dose for you.

If you receive more [invented name] than you should
An overdose is unlikely because you will only receive a single dose by a doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Severe side effects:

Tell the healthcare staff immediately if you experience any of the following severe side effects.

- Allergic reaction (rare: it may affect up to 1 in 1,000 people) with symtoms as:
    - Skin rash with itching or a burning feeling
- Angiooedema (frequency cannot be estimated from the available data) with symtoms as:
    - Swelling of the face, tongue or throat; difficulty swallowing; hives and breathing difficulties

Most side effects occur immediately. Some side effects affecting the skin, like itiching or rash, may however be delayed and occur up to several days after receiving the injection.

Other side effects:
Common: may affect up to 1 in 10 people
- Pain
- Widening of blood vessels (feeling of warmth)
- Numbness and tingling

Uncommon: may affect up to 1 in 100 people
- Unusual weakness
- Back pain
- Injection site reactions
- Chest pain
- Vomiting
- Nausea (feeling sick)
- Headache
- Altered sense of taste
- Severe itching
- Skin rash

Rare: may affect up to 1 in 1,000 people
- High blood pressure
- Inflammation of a vein
- Convulsion
- Reduced feeling of sensitivity, especially in the skin
- Anxiety
- Dizziness
- Altered sense of smell
- Breathing difficulties
- Increased coughing
- Runny nose
- Skin rash with itching or a burning feeling (eczema)
- Hives (nettle-type rash)

Not known: frequency cannot be estimated from the available data,
- Anaphylactoid shock and anaphylactoid reaction like feeling lightheaded or faint, fast, shallow breathing, wheezing, fast heartbeat, clammy skin, confusion and anxiety, collapsing or losing consciousness and other allergy symptoms,
- Loss of consciousness and depressed level of alterness
- Redness and irritation of the thin membrane that covers the eye
- Sudden, unexpected stopping of the heart, accelerated heartbeat
- Circulatory, collapse, low blood pressure or flushing
- Stomach pain
- Perspiration
- Redness of the skin
- Feeling hot
- Swelling of the face, tongue or throat

- Difficulty swallowing
- Transient change of labor and blood parameter, like factor XI activity, iron and ferritin, seen in blood tests only.

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.
[To be completed nationally]

5. How to store [invented name]

Keep this medicine out of the sight and reach of children.

You will not have to store this product yourself.

The following information is intended for healthcare staff only:
Do not freeze.
Do not use this medicine after the expiry date and time which is stated on the vial and on the carton.

6. Contents of the pack and other information

What [invented name] contains
- The active substance is ferucarbotran. Each ml contain 540 mg ferucarbotran (corresponding to 28 mg or 0.5 mmol iron).
- The other ingredients are (S)-lactic acid (E270), mannitol (E421), sodium hydroxide (E524) (for pH adjustment), and water for injections

What [invented name] looks like and contents of the pack
[invented name] suspension for injection is a reddish-brown liquid filled in a glass vial and closed with a fluorinated bromobutyl rubber stopper.

The contents of the pack are:
1 vial of 1.5 ml

Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>

This medicinal product is authorised in the Member States of the EEA under the following names:

Germany	Resotran 540 mg/ml Injektionssuspension
Sweden	Resotran
Austria	Resotran 540 mg/ml Injektionssuspension
Czech Republic	Resotran 540 mg/ml injekční suspense
Estonia	To be completed nationally
Spain	Resotran 540 mg/ml suspensión inyectable
France	CLENARTA 0,5 mmol Fe/mL, suspension injectable
Croatia	Resoxtran 540 mg/ml suspenzija za injekciju
Latvia	Resotran 540 mg/ml suspensija injekcijām
Portugal	Resotran 540 mg/ml suspensão injetável

This leaflet was last revised in 16 February 2026.

The following information is intended for healthcare professionals only:

After long standing of the preparation slight colour changes (dark to middle brown) may be observed, which disappear during normal handling. Inspect vial visually for damage and sediment before use. Use only those containing sediment-free homogeneous solution.

- Administration

[invented name] is to be administered through a large-bore needle or indwelling catheter (18-20 gauge is recommended) with connecting tube, if required.
To ensure proper placement of the injection needle, it is recommended to inject sterile 9 mg/ml (0.9%) saline solution before the administration of [invented name].

After the injection of the contrast medium the connective tubing and the needle should be flushed using sterile 9 mg/ml (0.9%) saline solution.

- Handling

[invented name] is a ready to use aqueous suspension for injection and should not be diluted. Vial containing contrast agents are intended for single use. [invented name] may not be drawn into the syringe until immediately before use.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.