

PACKAGE LEAFLET: INFORMATION FOR THE USER

LUMIREM**Oral suspension**

suspension of siloxane-coated superparamagnetic iron oxide crystals

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What LUMIREM is and what it is used for
2. Before you use LUMIREM
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4. Possible side effects
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1. WHAT LUMIREM IS AND WHAT IT IS USED FOR

LUMIREM is a diagnostic agent. It belongs to the group of contrast agents used for magnetic resonance imaging (MRI) and it contains iron.

LUMIREM is used to enhance the contrast of the images obtained during MRI examinations of the stomach and bowels.

This medicine is for diagnostic use only.

2. BEFORE YOU USE LUMIREM

You should read the information in this section carefully. You and your doctor should take into consideration the information given before you take LUMIREM

Do not use LUMIREM if

- you are allergic to iron or any of the other ingredients of LUMIREM
- you have a pacemaker
- you have a clip on a blood vessel
- you have an infusion pump
- you have a nerve stimulator
- you have a cochlear implant (implant in the inner ear)
- you have any suspected metallic foreign bodies, particularly in the eye.

Take special care with LUMIREM

You should inform your doctor if you suffer of asthma, since LUMIREM may aggravate symptoms of the existing disease.

Inform your doctor of any recent examination you may have had with LUMIREM if he/she wants you to have a laboratory test for iron done.

Remove all metallic objects you may be wearing before the examination. Inform your doctor if you have:

- a pacemaker
- a clip on a blood vessel
- an infusion pump
- a nerve stimulator
- a cochlear implant (implant in the inner ear)
- any suspected metallic foreign bodies, particularly in the eye.

This is important as these can result in serious problems, as magnetic resonance imaging devices use very strong magnetic fields.

Taking other medicines

Please inform your doctor or pharmacist of any disease you might have and if you are taking or have recently taken any other medicines, even those not subject to medical prescription. Be particularly careful if you take medicines for high blood pressure.

Taking LUMIREM with food and drink

There are no known interactions between LUMIREM and food and drinks. However, please check with your doctor or pharmacist if it is required not to eat or drink before the examination.

Pregnancy and breast-feeding

Inform your doctor if you are pregnant, might be pregnant, or if your period is late.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

LUMIREM is unlikely to affect your ability to drive or use machines. If you feel unwell after the examination, you should not drive or use machines.

Important information about some of the ingredients of LUMIREM

List of the ingredients with a known effect: methyl parahydroxybenzoate (E 218), propyl parahydroxybenzoate (E 216), sunset yellow colouring agent (E 110), sorbitol (E 420) and sodium.

Sodium diet

This medicinal product contains 100 mg of sodium (salt) per 100 mL. Take this into account in case you are on a low sodium diet.

Intolerance to sorbitol

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Allergy to dye yellow-orange S (E110)

This product may cause allergic reactions.

3. HOW TO USE LUMIREM

LUMIREM is an oral suspension.

The recommended dose in adults is 900 ml. This dose may be adjusted by your doctor, but at least 600 ml is generally necessary. The dose is administered in three portions during the hour before examination.

4. POSSIBLE SIDE EFFECTS

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

LUMIREM contains 26g of sorbitol per 300 mL, which can be expected to cause gastric upsets:

The side effects most commonly occurring during administration of LUMIREM are gastrointestinal disorders and transient prickling sensations in the mouth. Allergic reactions are possible.

The side effects reported for LUMIREM are mentioned below and their frequency is unknown:

- allergic reactions (hypersensitivity) can be serious in nature occurring within 60 min after the administration such as anaphylactic reaction or delayed occurring up to 7 days after administration of product, recognizable by spots, itching, sudden swelling of the face and neck that can cause breathing difficulties,
- prickling sensation
- diarrhoea, abdominal pain, nausea, abdominal distension, flatulence, pain in the upper abdomen
- cold sensation

Side effects in children:

The side effects of Lumirem in children are the same as those in adults.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE LUMIREM

Keep out of the reach and sight of children.

LUMIREM must be stored below 25°C

Do not use LUMIREM after the expiry date which is stated on the bottle and on the carton, after the abbreviation "Exp".

The expiry date refers to the last day of that month.

It is unlikely that you will be asked to dispose of any left over LUMIREM. If this happens ask your pharmacist what you should do. These measures will help to protect the environment.

6. FURTHER INFORMATION

What LUMIREM contains

- The active substance is a suspension of siloxane-coated superparamagnetic iron oxide crystals.
- The other ingredients are methylparahydroxybenzoate (E 218), propylparahydroxybenzoate (E 216), carmellose sodium, sunset yellow colouring agent (E 110), orange flavour, ammonium glycyrrhizinate, sodium saccharin, 70% crystallisable sorbitol, sodium chloride, sodium hydroxide, purified water. (see also section 2 'Important information about some of the ingredients of LUMIREM')

What LUMIREM looks like and contents of the pack

LUMIREM is an orange-brown to orange oral solution for oral administration.

The LUMIREM pack contains 1 or 3 bottles with 300 ml of suspension.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

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