

Package Leaflet: Information for the Patient

IELMAG3 0.2 mg kit for radiopharmaceutical preparation

Mertiatide (mercaptoacetyltriglycine)

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 nuclear medicine doctor who will supervise the procedure.
- If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What IELMAG3 is and what it is used for
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1. What IELMAG3 is and what it is used for

This medicine is a radiopharmaceutical product for diagnostic use only.

IELMAG3 is used to study the function and structure and blood flow of the kidneys as well as function of the urinary tract, by making an image of these organs. After the medicine is injected, it temporarily collects in certain parts of the body. This radiopharmaceutical substance contains a small amount of radioactivity, which can be detected from outside of the body by using special cameras. Your nuclear medicine doctor will then take an image (scintigraphy) of the concerned organs which can give your doctor valuable information about the structure and the function of these organs.

The use of IELMAG3 does involve exposure to small amounts of radioactivity. Your doctor and the nuclear medicine doctor have considered that the clinical benefit you will obtain from the procedure with the radiopharmaceutical outweighs the risk due to radiation.

2. What you need to know before IELMAG3 is used

IELMAG3 must not be used

if you are allergic (hypersensitive) to mertiatide (mercaptoacetyltriglycine) or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Take special care with IELMAG3

- if you are pregnant or believe you may be pregnant
- if you are breast-feeding
- if you are under 18 years old

Please talk to your nuclear medicine doctor if any of the above applies to you. This medicine may not be suitable for you. Your nuclear medicine doctor will advise you.

Before administration of IELMAG3 you should

drink plenty of water before the start of the examination in order to urinate as often as possible during the first hours after the study.

Children and adolescents

Talk to your nuclear medicine doctor if you are under 18 years old.

Other medicines and IELMAG3

Tell your nuclear medicine doctor if you are taking, have recently taken or might take any other medicines.

IELMAG3 with drink

Please see section 2 „Before administration of IELMAG3 you should“.

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 nuclear medicine doctor for advice before you are given this medicine.

You must inform the nuclear medicine doctor before the administration of IELMAG3 if there is a possibility you might be pregnant, if you have missed your period or if you are breast-feeding. When in doubt, it is important to consult your nuclear medicine doctor who will supervise the procedure.

If you are pregnant

The nuclear medicine doctor will only administer this product during pregnancy if a benefit is expected which would outweigh the risks.

If you are breast-feeding

Resuming breast-feeding should be in agreement with the specialist in Nuclear Medicine. Please ask your doctor or the specialist physician in Nuclear Medicine who will supervise the procedure before taking any medicines.

Driving and using machines

It is considered unlikely that IELMAG3 will affect your ability to drive and use machines after the investigation.

IELMAG3 contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per kit [vial (1) and vial (2)], that is to say essentially 'sodium-free'.

3. How IELMAG3 is used

There are strict laws on the use, handling and disposal of radiopharmaceutical products.

IELMAG3 will only be used in special controlled areas. This product will only be handled and given to you by people who are trained and qualified to use it safely. These persons will take special care for the safe use of this product and will keep you informed of their actions.

The nuclear medicine doctor supervising the procedure will decide on the quantity of IELMAG3 to be used in your case. It will be the smallest quantity necessary to get the desired information.

The quantity to be administered usually recommended for an adult ranges from 40 to 200 MBq (megabecquerel, the unit used to express radioactivity).

Use in children and adolescents

In children and adolescents, the quantity to be administered will be adapted to the child's weight.

Administration of IELMAG3 and conduct of the procedure

You will be asked to drink plenty of water and empty your bladder immediately before the examination starts.

IELMAG3 is administered by intravenous administration.

The scintigraphy is usually started immediately after administration.

Duration of the procedure

Your nuclear medicine doctor will inform you about the usual duration of the procedure.

After administration of IELMAG3, you should:

- avoid any close contact with young children for the 24 hours following the injection,
- urinate frequently in order to eliminate the product from your body.

The nuclear medicine doctor will inform you if you need to take any special precautions after receiving this medicine. Contact your nuclear medicine doctor if you have any questions.

If you have been given more IELMAG3 than you should

An overdose is unlikely because you will only receive a single dose of IELMAG3 precisely controlled by the nuclear medicine doctor supervising the procedure.

However, in the case of an overdose, you will receive the appropriate treatment. In particular, the nuclear medicine doctor in charge of the procedure may recommend that you drink abundantly to facilitate the elimination of IELMAG3 from your body.

Should you have any further question on the use of IELMAG3, please ask the nuclear medicine doctor who supervises the procedure.

4. Possible side effects

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

Side effects with frequency very rare (may affect up to 1 in 10,000 patients):

- Mild **allergic reactions** including with symptoms such as hives, rash, swelling of the eyelids and coughing.

Side effects with frequency not known (cannot be estimated from the available data):

- Mild **circulatory reactions** with symptoms such as sudden dizziness or fainting.

This administered radiopharmaceutical will deliver low amounts of ionising radiation associated with the least risk of cancer and hereditary abnormalities. Your doctor has considered that the clinical benefit that you will obtain from the procedure with the radiopharmaceutical overcomes the risk due to radiation.

Reporting of side effects

If you get any side effects talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to:

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How IELMAG3 is stored

You will not have to store this medicine. This medicine is stored under the responsibility of the specialist in appropriate premises.

Storage of radiopharmaceuticals will be in accordance with national regulation on radioactive materials.

The following information is intended for the specialist only.

IELMAG3 must not be used after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Storage conditions:

Kit: Store in a refrigerator (2 - 8 °C).

Store in the original package in order to protect from light.

Shelf life after first opening and radiolabelling:

8 hours when stored below 25 °C.

6. Contents of the pack and other information

What IELMAG3 contains

The active substance is 0.2 mg mertiatide (mercaptoacetyltriglycine) in vial (1).

The other ingredients are:

Vial (1):

Stannous chloride dihydrate,
Disodium (R,R)-tartrate dihydrate,
Sodium hydroxide,
Hydrochloric acid

Vial (2):

Sodium monohydrogenphosphate dihydrate,
Sodium dihydrogenphosphate dihydrate,
Hydrochloric acid,
Water for injection

What IELMAG3 looks like and contents of the pack

The product is a kit for radiopharmaceutical preparation.
IELMAG3 consists of two different 10 ml glass vials which cannot be used separately.
Vial (1) contains IELMAG3 powder and vial (2) contains IELMAG3 solution.

Pack size: 5 Kits [vial (1) and vial (2)]

Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised in 12/2025.

The following information is intended for medical or healthcare professionals only:

The complete Summary of Product Characteristics (SmPC) of IELMAG3 is provided as a tear-off section at the end of the printed leaflet in the product package, with the objective to provide healthcare professionals with other additional scientific and practical information about the administration and use of this radiopharmaceutical.

Please refer to the SmPC.