

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

IELMAG3 0.2 mg kit for radiopharmaceutical preparation

Mertiatide (mercaptoacetyltriglycine)

Read all of this leaflet carefully before you will be administered this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your referring doctor or the specialist physician in Nuclear Medicine who will supervise the procedure.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your referring doctor or the specialist physician in Nuclear Medicine who has supervised the procedure.

In this leaflet:

1. What IELMAG3 is and what it is used for
2. Before IELMAG3 is administered
3. How IELMAG3 will be used
4. Possible side effects
5. How IELMAG3 is stored
6. Contents of the pack and other information

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 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 that you will obtain from the procedure with the radiopharmaceutical outweighs the risk due to radiation.

2. BEFORE IELMAG3 IS ADMINISTERED

IELMAG3 must never be used

- if you are allergic (hypersensitive) to mertiatide (mercaptoacetyltriglycine) or any of the other ingredients of IELMAG3 or to any of the components of the labelled radiopharmaceutical.

Take special care with IELMAG3

Inform the specialist in Nuclear Medicine in the following cases:

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

Your nuclear medicine doctor will inform you if you need to take any special precautions after using this medicine. Talk to your nuclear medicine doctor if you have any questions.

Taking other medicines

Please tell your doctor or the specialist physician in Nuclear Medicine who will supervise the procedure if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking IELMAG3 with food and drink

Drink plenty of water before the examination starts.

Pregnancy and breast-feeding

You must inform the specialist physician in Nuclear Medicine 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 physician or the specialist physician in Nuclear Medicine who will supervise the procedure.

If you are pregnant

Your physician will only consider this examination during your pregnancy in case of absolute necessity.

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.

Before IELMAG3 administration you should:

- drink plenty of water before the start of the examination in order to allow optimal results of the investigation.

After administration of IELMAG3 has been performed, you should:

- avoid any close contact with young children for the 12 hours following the injection
- urinate frequently in order to eliminate the product from your body

There are strict laws on the use, handling and disposal of radiopharmaceutical products. IELMAG3 will only be used in a hospital. 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.

Driving and using machines

It is considered unlikely that IELMAG3 will affect your ability to drive or to operate machinery.

3. HOW WILL IELMAG3 BE 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 usually recommended to be administered for an adult ranges, depending on the test to perform between 40 and 200 MBq (megabequerel, the unit 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 physician will inform you about the usual duration of the procedure.

If you have been administered more IELMAG3 than you should

An overdose is almost impossible 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 your doctor or the specialist physician in Nuclear Medicine who supervises the procedure.

4. POSSIBLE SIDE EFFECTS

Like all medicines, IELMAG3 can cause side effects, although not everybody gets them.

This administered radiopharmaceutical will deliver low amount of ionising radiation with very low risk of cancer and hereditary abnormalities. Mild allergic reactions, characterised by hives, rash, swelling of the eyelids and coughing have been reported very rarely in less than 1 out of 10,000 patients. Occasionally a circulatory disorder of a mild nature (characterized by sudden dizziness or fainting) has been reported. Your doctor has considered that the clinical benefit that you will obtain from the procedure with the radiopharmaceutical overcomes the risk due to radiation. If you notice any side effects, or if you notice any side effects not listed in this leaflet, please tell your doctor or the specialist physician in Nuclear Medicine who supervises the procedure.

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 via the national reporting system to:

Ireland

Pharmacovigilance Section

Irish Medicines Board

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6767836

Website: www.imb.ie

e-mail: imbpharmacovigilance@imb.ie

By reporting side effects you can help to 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:

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:

After radiolabelling: 8 hours.

Store the radiolabelled preparation 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,

Nitrogen as protective gas

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.

It consists of 2 different vials, 5 of each kind in one box.

Vial (1) contains a powder with 0.2 mg of the active substance mertiatide; vial (2) contains 2.5 ml of phosphate buffer solution.

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

United Kingdom:	IELMAG3 0.2 mg kit for radiopharmaceutical preparation
Ireland:	IELMAG3 0.2 mg kit for radiopharmaceutical preparation
Austria:	Mertioscan 0,2 mg Kit für ein radioaktives Arzneimittel
Bulgaria:	IELMAG3 0.2 mg kit for radiopharmaceutical preparation

This leaflet was last approved in 08/2016.