

PATIENT INFORMATION LEAFLET

PENTACIS

Kit for the preparation of technetium (^{99m}Tc) pentetate injection

Calcium trisodium pentetate

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or your 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. See section 4.

In this leaflet:

- 1. What PENTACIS is and what it is used for**
- 2. Before you take PENTACIS**
- 3. How to take PENTACIS**
- 4. Possible side effects**
- 5. How to store PENTACIS**
- 6. Further information**

1. WHAT PENTACIS IS AND WHAT IT IS USED FOR

This medicinal product is for diagnostic use only.

This product is a powder which, when mixed with a solution of the radioactive substance sodium pertechnetate (^{99m}Tc) forms technetium (^{99m}Tc) pentetate.

Technetium (^{99m}Tc) pentetate injection is a diagnostic radiopharmaceutical for isotopic exploration. This is a product which, when administered, temporarily collects in a particular organ of the body. Because the substance contains a small amount of radioactivity it can be detected from outside the body using special cameras, and a picture, known as a scan, can be taken. This scan will show exactly the distribution of the radioactivity within the organ and the body. This can give the physician valuable information about the structure and function of that organ.

When injected, technetium (^{99m}Tc) pentetate can be used to examine either the kidneys or the brain. This normally involves a scan of the relevant area. The functioning of the kidneys can also be investigated by measurement of the radioactivity excreted in the urine.

If inhaled, technetium (^{99m}Tc) pentetate will provide a scan of the lungs and, if ingested, it can be used to evaluate gastric function.

2. BEFORE YOU TAKE PENTACIS

Do not take PENTACIS

- if you are allergic (hypersensitive) to calcium trisodium pentetate or any of the other ingredients of PENTACIS.

Take special care with PENTACIS

Radioactive medicine.

The use of technetium (^{99m}Tc) pentetate does involve administration of small amounts of radioactivity. The risk this involves is very small and your physician will not consider carrying out the investigation unless he believes that the risk is outweighed by the potential benefit of the study.

Because some cases of allergic type reactions have been reported after administration of technetium (^{99m}Tc) pentetate, you should tell your physician if you already experienced allergic reaction.

Precautions for Use

To prevent accumulation of technetium (^{99m}Tc) pentetate in the bladder you will be asked to drink and to urinate frequently.

Your physician will inform you if you need to take any further special precautions after use of this product.

Taking other medicines

Some medicines may affect the quality of the results obtained from technetium (^{99m}Tc) pentetate examinations.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

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

It is important to tell your physician if there is any possibility that you are pregnant. Special consideration is given to the use of radiopharmaceuticals during pregnancy. Your physician will only use this product if he considers that the benefit outweighs the risk.

Tell your physician if you are breast-feeding as he may delay the investigation until breast-feeding is completed or ask you to stop breast-feeding for a short while until the radioactivity is no longer in your body.

3. HOW TO TAKE PENTACIS

Your physician will decide on the amount of technetium (^{99m}Tc) pentetate to be used. Doses may be between 1.8 to 1000 MBq (Megabecquerel is the unit in which radioactivity is measured), depending on the type of investigation, on the route by which it is to be administered.

Lower doses may be used for children.

Technetium (^{99m}Tc) pentetate is administered by injection into a vein, or by inhalation using a nebulizer. It can also be swallowed as a liquid.

A single administration is sufficient to provide your physician with the information needed.

Studies may be performed at any time from the beginning of the injection, depending on the type of study which is to be performed.

If you take more PENTACIS than you should

Since technetium (^{99m}Tc) pentetate is administered by a physician under strictly controlled conditions there is little chance of possible overdose.

4. POSSIBLE SIDE EFFECTS

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

In a very small number of patients, allergic type reactions have been notified.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

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

5. HOW TO STORE PENTACIS

Because there are strict laws covering the use, handling, storage and disposal of radioactivity, this product will always be used in a hospital or a similar setting. It will only be handled and administered by people who are trained and qualified in the safe handling of radioactive material and there are no additional precautions which are your responsibility.

Keep out of the reach and sight of children.

Do not use PENTACIS after the expiry date which is stated on the labels after EXP. The expiry date refers to the last day of that month.

The kit and the labelled product should be stored at 2°C – 8°C, in a refrigerator.

6. FURTHER INFORMATION

What PENTACIS contains

- The active substance is: calcium trisodium pentetate.
Each vial contains 9.1 mg of pentetate.
- The other ingredients are: stannous chloride dihydrate, sodium chloride.

What PENTACIS looks like and contents of the pack

You will not have to get this medicine or handle the packaging or the vial. The following data are for your information only.

PENTACIS is a soluble powder for injection which should be dissolved and labeled with radioactive technetium (^{99m}Tc) before use. When this powder is mixed with a solution of pertechnetate (^{99m}Tc) of sodium, a solution of technetium (^{99m}Tc)-pentetate is formed. This solution is ready to be injected intravenously.

Packsize: kit for radiopharmaceutical preparation containing 5 multidose vials.

Manufacturer and Marketing Authorisation Holder

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For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

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