

PACKAGE LEAFLET: INFORMATION FOR THE USER

Myoview 230 micrograms kit for radiopharmaceutical preparation

Tetrofosmin

Read all of this leaflet carefully before you are given Myoview, 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.
- 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.

In this leaflet:

1. What Myoview is and what it is used for
2. What you need to know before you are given Myoview
3. How to use Myoview
4. Possible side effects
5. How to store Myoview
6. Contents of the pack and other information

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

This medicine is for diagnostic use only. It is used only to help identify illness.

Myoview is a ‘radio-pharmaceutical’ medicine. It is given before a scan and helps a special camera see inside a part of your body.

- It contains an active ingredient called ‘tetrofosmin’. This is mixed with a radioactive ingredient called ‘technetium 99m’ before it is used.
- Once injected it can be seen from outside your body by a special camera used in the scan.
- The scan can help your nuclear medicine doctor see how well the heart is working, or see damage to the heart after a heart attack.
- Some other people are given this medicine before a scan to look at lumps in the breast.

Your nuclear medicine doctor will explain which part of your body will be scanned.

The use of Myoview 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. Ask your nuclear medicine doctor if you have any questions.

2. What you need to know before you are given Myoview

Do not use Myoview: • If you are allergic (hypersensitive) to **Myoview** or any other ingredient. (Listed in Section 6).

- If you are pregnant or think you might be pregnant.

Do not take Myoview if any of the above applies to you. If you are not sure talk to your nuclear medicine doctor.

Warnings and Precautions Talk to your nuclear medicine doctor before using Myoview:

- The person who will be given this medicine is a child or adolescent.
- You have missed your last period. This may indicate that you are pregnant and therefore

- ✓ unable to be given Myoview (see section Pregnancy and breast-feeding).
- ✓ You are on a low sodium diet.
- ✓ You are breast-feeding.

Before administration of Myoview 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 scan.

Children and adolescents

Efficacy and safety in patients below 18 years has not been established.

Other medicines and Myoview

Please tell your doctor nuclear medicine who will supervise the procedure if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because some medicines can affect the way Myoview works. If you are having a heart scan tell your nuclear medicine doctor if you are taking any of the types of medicine below. This is because they may affect the results of your scan:

- Beta blockers such as atenolol, bisoprolol or propranolol.
- Calcium channel blockers such as nifedipine, diltiazem or felodipine.
- Nitrates such as glyceryl trinitrate, isosorbide mononitrate or isosorbide dinitrate.
- Any medicines for your blood pressure, your heart or heart failure.

If you are not sure if any of the above applies to you, talk to your nuclear medicine doctor before having Myoview.

Having Myoview with food and drink

If you are having:

- A **heart scan** - you may be asked not to eat the night before. Or you may be asked to have only a light breakfast on the morning of the scan.
- A **breast scan** - you can eat and drink liquids normally.

Pregnancy and breast-feeding

You should not be given Myoview if you are pregnant or think you may be pregnant. This is because it may affect the baby.

Do not breast-feed if you are given Myoview. This is because small amounts of 'radioactivity' may pass into the mother's milk. If you are breast-feeding, your nuclear medicine doctor may wait until you have finished breast-feeding before using Myoview. If it is not possible to wait your nuclear medicine doctor will ask you to:

- stop breast-feeding for 3 to 6 hours, and
- use formula feed for your child, and
- express (remove) breast milk and throw away the milk.

Your nuclear medicine doctor will let you know when you can start breast-feeding again.

Driving and using machines

It is considered unlikely that Myoview will affect your ability to drive or to use machines. Ask your nuclear medicine doctor if you can drive or use machines after you have been given Myoview.

Myoview contains sodium

This medicine contains 15 – 29 mg sodium (main component of cooking/table salt) per reconstituted vial. This is equivalent to 0.7 – 1.4% of the recommended maximum daily dietary intake of sodium for an adult.

When Myoview is used you are exposed to radioactivity.

- Your nuclear medicine doctor will always consider the possible risks and benefits before you are given the medicine.

Ask your nuclear medicine doctor if you have any questions.

3. How to use Myoview

There are strict laws on the use, handling and disposal of radiopharmaceutical products. Myoview will be given to you by a specially trained and qualified person.

- Myoview will always be used in a hospital or clinic.
- They will tell you anything you need to know for its safe use.

The dose you are given depends on the type of scan you are having. Your nuclear medicine doctor will decide on the dose that is best for you. It will be the smallest dose necessary to get the desired information.

Administration of Myoview and conduct of the procedure

For a heart scan the usual dose is:

- One injection after you have rested.
- A second injection (after at least one hour), when your heart is working harder than normal. Such as during or just after exercise.

The order of the two injections may be the opposite way round for some people. Other people only need one injection. In some cases your nuclear medicine doctor may decide that it is best to give the two injections on separate days.

For a breast scan the usual dose is:

- One single injection.

If you are given more Myoview than you should

Myoview is given in a hospital or clinic by a specially trained and qualified person. It is unlikely that you will be given too much. However, in the case of an overdose, you will receive the appropriate treatment. If you have any concerns talk to your nuclear medicine doctor.

Duration of the procedure

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

After administration of Myoview, you should:

- 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 the nuclear medicine doctor if you have any questions.

4. Possible side effects

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

This radiopharmaceutical will deliver low amounts of ionising radiation with the least risk of cancer and hereditary abnormalities.

Serious side effects

If you have an allergic reaction when you are in hospital or a clinic having the scan, tell the nuclear medicine doctor straight away. The signs and symptoms may include:

Uncommon – may affect up to 1 in 100 people

- Flushing

Rare – may affect up to 1 in 1000 people

- skin rash

Not known – frequency cannot be estimated from the available data

- itching, redness or hives
- swelling of the face, local swelling
- difficulty breathing, wheezing, throat tightness, coughing

In more severe cases (severe allergic reaction or anaphylaxis), reactions may include:

- passing out (unconsciousness), feeling dizzy or lightheaded.

If any of the side effects above happen after you leave the hospital or clinic, go straight to the casualty department of your nearest hospital.

Other side effects include

Uncommon – may affect up to 1 in 100 people

- changes in taste, such as a metallic taste
- uncomfortable feeling of warmth beginning where the injection was given
- vomiting

Rare – may affect up to 1 in 1000 people

- changes in smell
- visual impairment
- abdominal pain, feeling sick (nausea), burning sensation in mouth

Not known – frequency cannot be estimated from the available data

- headache, dizziness
- heart pounding (palpitations), chest pain
- fever
- white blood cell count increased (seen in certain types of blood test)

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

United Kingdom via:

The Yellow Card Scheme at

Website: www.mhra.gov.uk/yellowcard.

Ireland to:

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 Myoview

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.

Hospital staff will ensure that the product is stored and disposed of correctly and not used after the expiry date stated on the label.

This following information is intended for healthcare or medical professionals only.⁵

Keep this medicine out of the sight and reach of children

- Do not use Myoview after the expiry date which is stated on the label, after EXP.
- Store the product in refrigerator at 2-8°C. Store in the original package in order to protect from light.
- Chemical and physical in-use stability of the reconstituted solution for injection has been demonstrated for 12 hours at 2-25°C. Store the reconstituted product below 25°C. Do not freeze.

6. Further information

Contents of the pack and other information

This following information is intended for healthcare or medical professionals only. What Myoview contains

- The active ingredient is tetrofosmin. Each vial of Myoview contains 230 micrograms of tetrofosmin.
- The other ingredients are stannous chloride dihydrate, disodium sulphosalicylate, sodium D-gluconate and sodium hydrogen carbonate.

What Myoview looks like and contents of the pack

Myoview is a kit for radio-pharmaceutical preparation; it is supplied as a single colourless glass vial containing a powder for solution for injection. Pack sizes of 2 or 5 vials are available, not all pack sizes may be marketed.

Marketing Authorisation Holder

United Kingdom:
GE Healthcare Limited
Pollards Wood
Nightingales Lane
Chalfont St Giles
Buckinghamshire HP8 4SP
United Kingdom

Ireland:
GE Healthcare AS
P.O.Box 4220 Nydalen
NO-0401 Oslo
Norway

Manufacturer

GE Healthcare AS
Nycoveien 1
NO-0485 Oslo
Norway

This leaflet was last revised in June 2023.

Marketing Authorisations

UK: PL 00221/0142
Ireland: PA 735/012/001
Myoview is a trademark of GE Healthcare.

GE and the GE Monogram are trademarks of General Electric Company.