PATIENT INFORMATION LEAFLET

Mediam Stannous Agent 4 milligrams/6.8 milligrams kit for radiopharmaceutical preparation
(called Mediam Stannous Agent in this leaflet)
Stannous fluoride/methylene diphosphonic acid, as sodium salt

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

In this leaflet:

1. WHAT MEDIAM STANNOUS AGENT IS AND WHAT IT IS USED FOR

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

Mediam Stannous Agent is a radiopharmaceutical medicine. It is given before a scan and helps a special camera see inside a part of your body.
- It contains active ingredients called stannous fluoride and methylene diphosphonic acid, as sodium salt. These are taken with another ingredient called technetium.
- Once injected it can be seen from outside your body by a special camera used in the scan.
- The scan can help your doctor see how well your heart is working and how well the blood is flowing to organs in your body.
- Some other people are given this medicine to find bleeding in the gut.

Your doctor or nurse will explain which part of your body will be scanned.

2. WHAT YOU NEED TO KNOW BEFORE MEDIAM STANNOUS AGENT IS USED

You should not be given Mediam Stannous Agent:
- If you are allergic (hypersensitive) to the active ingredients (listed in Section 6).

Do not have Mediam Stannous Agent if the above applies to you. If you are not sure talk to your doctor or nurse.

Take special care with Mediam Stannous Agent
Check with your doctor or nurse before having Mediam Stannous Agent:
- If you are pregnant or think you might be pregnant.
- If you are on a low sodium diet.

Taking other medicines
Please tell your doctor or nurse 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 Mediam Stannous Agent works.

Before your scan tell your doctor or nurse 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 propanolol (used to treat conditions such as high blood pressure, heart disease, anxiety and tremor).
- Calcium channel blockers, such as verapamil or nifedipine (used to treat high blood pressure and angina).
- Nitrates, such as glyceryl trinitrate (used to treat angina).
- Anthracycline antibiotics such as daunorubicin and doxorubicin (used in chemotherapy).
- Heparin (used to prevent clotting of the blood).
- Prazosin (used to lower high blood pressure or to treat symptoms of an enlarged prostate gland).
- Methyldopa (used for low blood pressure).
- Hydralazin (used to treat high blood pressure).
- Quinidine (used for an irregular heart beat).
- Medicines containing or similar to digitalis (for example, digoxin, used to treat an irregular heartbeat).
- Medicines given in hospital for x-rays or scans (iodinated contrast media).
- Aluminium (aluminium salts are contained in some medicines for indigestion and heartburn; aluminium salts may also be used in some illnesses of the kidney).
- Tin overload.

If you are not sure if any of the above applies to you, talk to your doctor or nurse before having Mediam Stannous Agent.

Your scan may be affected if you are using a teflon ‘catheter’ (used to allow the flow of fluids or expand a passageway in the body). Talk to your doctor or nurse if this applies to you.

Pregnancy and breast-feeding
You must tell your doctor if you are pregnant or think you may be pregnant. Your doctor will only use this product if it is considered that the benefit outweighs the risk.

Do not breast-feed if you are given Mediam Stannous Agent. This is because small amounts of ‘radioactivity’ may pass into the mother’s milk. If you are breast-feeding, your doctor may wait until you have finished breast-feeding before using Mediam Stannous Agent. If it is not possible to wait your doctor will ask you to:
- stop breast-feeding for 12 hours, and
- use formula feed for your child, and
- express (remove) breast milk and throw away the milk.

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

Driving and using machines
Ask your doctor if you can drive or use machines after you have been given Mediam Stannous Agent.

Important information about Mediam Stannous Agent
When Mediam Stannous Agent is used you are exposed to radioactivity. Your doctor will always consider the possible risks and benefits before you are given the medicine.

Ask your doctor if you have any questions.

3. HOW MEDIAM STANNOUS AGENT IS USED

Mediam Stannous Agent will be given to you by a specially trained and qualified person.
- Mediam Stannous Agent will always be used in a hospital or clinic.
- They will tell you anything you need to know for its safe use.

Your doctor will decide on the dose that is best for you.

The usual dose:
- Two injections.

The first injection will contain Mediam Stannous Agent. This will be followed, 20 to 40 minutes later, by a second injection containing the ingredient technetium. Alternatively your doctor may decide to take a sample of your blood 15 to 30 minutes after the first injection. Your blood sample will be mixed with technetium then given to you as an injection.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Mediam Stannous Agent can cause side effects, although not everybody gets them.

Allergic reactions
If you have an allergic reaction when you are in hospital or a clinical having the scan, tell the doctor or nurse straight away. The signs include:
- skin rash or itching or flushing
- swelling of the face
- difficulty in breathing.

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
- headache
- dizziness (due to fall in blood pressure)
- nausea (feeling sick)
- vomiting (being sick)
- malaise (feeling of becoming ill)
- swelling of the hands and feet (extremities)
- pain in joints.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the 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 MEDIAM STANNOUS AGENT IS STORED
Mediam Stannous Agent is kept out of the reach and sight of children.
The product label includes the correct storage conditions and the expiry date for the batch.
Hospital staff will ensure that the product is stored and disposed of correctly and not used after the expiry date stated on the label.

6. CONTENTS OF THE PACK AND OTHER INFORMATION
What Mediam Stannous Agent contains
The active ingredients are stannous fluoride and methylene diphosphonic acid, as sodium salt. Each vial of Mediam Stannous Agent contains 4 milligrams stannous fluoride and 6.8 milligrams methylene diphosphonic acid, as sodium salt.
There are no other ingredients in Mediam Stannous Agent.

What Mediam Stannous Agent looks like and contents of the pack
Mediam Stannous Agent is supplied as a kit for radiopharmaceutical preparation. The kit contains five vials. Each vial contains 4 milligrams of stannous fluoride and 6.8 milligrams of sodium medronate.

Marketing Authorisation Holder

MEDIAM
21, avenue de Verdun
F-59700 Marcq-en-Baroeul
Tel: +33 3 20 49 72 58
Fax: +33 3 20 88 16 71

Manufacturer
GIPHARMA S.r.l.
Str. per Crescentino
I - Saluggia (VC), 13040
Tel :+ 39 0161 487 141
Fax :+ 39 0161 487 140

MA number: PA 1229/002/001

This leaflet was last approved in 09/2017.

The following information is intended for medical or healthcare professionals only:
Please refer to the SmPC.