

PACKAGE LEAFLET: INFORMATION FOR THE USER

**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 Mediam Stannous Agent.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- 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 nurse.

In this leaflet:

1. What **Mediam Stannous Agent** is and what it is used for
2. Before you are given **Mediam Stannous Agent**
3. How **Mediam Stannous Agent** is given
4. Possible side effects
5. How to store **Mediam Stannous Agent**
6. Further information

**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. Before you are given Mediam Stannous
Agent**

**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 **propranolol** 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 apply 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**.

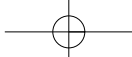
**Important information about Mediam
Stannous Agent**

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.

turn over ➤



3. How Mediam Stannous Agent is given

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.

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 nurse.

5. How to store Mediam Stannous Agent

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. Further 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
85 rue N. Mandela
59120 Loos
France

Manufacturer

GIPHARMA Srl
Via Crescentino
13040 Saluggia (Vc)
Italy

This leaflet was last approved in 08/2008.

Marketing Authorisations

UK: PL 22879/0003
Ireland: PA 1229/002/001

MEDIAM



PATIENT INFORMATION

Mediam Stannous Agent

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kit for radiopharmaceutical
preparation
Stannous fluoride/methylene
diphosphonic acid, as
sodium salt
N106K



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