Package Leaflet: Information for the patient

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

PoltechMDP, 5 mg,
kit for radiopharmaceutical preparation
methylenediphosphonic acid

What is in this leaflet

1. What PoltechMDP is and what it is used for
This medicine is a radiopharmaceutical product for diagnostic use only.
PoltechMDP after labelling with radioactive isotope of technetium (^{99m}Tc) is used for skeletal imaging.

The use of PoltechMDP 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. What you need to know before PoltechMDP is used

PoltechMDP must not be used
PoltechMDP must not be used if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Take special care with PoltechMDP
- if you are pregnant or believe you may be pregnant,
- if you are breastfeeding.

The administration of radiopharmaceuticals creates risks for other persons from external radiation or contamination from spill of urine, vomiting etc. Therefore basic hygiene rules should be observed according to national regulations.

Special caution should be exercised while handling, to avoid unnecessary radiation exposure to staff and patients.

Children and adolescents
Talk to your nuclear medicine doctor if you are under 18 years old.

Other medicines and PoltechMDP
Tell your doctor or nuclear medicine doctor who will supervise the procedure if you are taking or have recently taken or might take any other medicines, including medicines obtained without prescription.

An increased extraosseous accumulation of the radiotracer is reported for iron containing compounds, acute administration of diphosphonate, several cytostatic and immunosuppressive drugs, aluminium-containing antacids, X-ray contrast media, antibiotics, anti-inflammatory substances, injections of calcium gluconate, heparin calcium and γ-amino caproic acid.

PoltechMDP with food and drink
There are no special precautions.

Pregnancy and breastfeeding
You must inform the nuclear medicine doctor before the administration of PoltechMDP if:
- there is possibility you might be pregnant
- you have missed your period
- you are breastfeeding.

When in doubt, it is important to consult your doctor or the nuclear medicine doctor who will supervise the procedure.

If you are pregnant it is important to tell it your doctor. The use of radiopharmaceuticals during pregnancy should be considered carefully. The nuclear medicine doctor will only administer this product during pregnancy if a benefit is expected which would outweigh the risks.

If you are breastfeeding, and if the administration of radiopharmaceutical is considered necessary, your doctor can ask you to interrupt breastfeeding and to remove the milk from the breasts. Breastfeeding should be stopped for 4 hours after injection and the milk secreted during this period of time should be discarded. Please ask your nuclear medicine doctor when you can resume breastfeeding.

Driving and using machines
There are no studies on effect on your ability to drive or to use machines.

PoltechMDP contains sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per vial, i.e. essentially ‘sodium-free’.

3. How PoltechMDP is used
Radiopharmaceuticals may be administered only by authorized health-care personnel.

There are strict laws on the use, handling and disposal of radiopharmaceutical products. PoltechMDP 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.

This product is for intravenous use.

The nuclear medicine doctor supervising the procedure will decide on the quantity of product to be used in your case. It will be the smallest quantity necessary to get the desired information. The quantity to be administered, recommended for an adult

ranges between 370 and 740 MBq (megabecquerel, the unit used to express radioactivity), however other activities may also be used.

Use in children and adolescents
In children and adolescents, the quantity to be administered will be adapted to the child's weight.

Administration of PoltechMDP and conduct of the procedure
The ready to use solution for injection will be injected into a vein before the scan is taken. The scanning may take place within 2 or a few hours after injection, depending on the investigation.

Radioactive ^{99m}Tc-MDP preparation is designed for intravenous use only under a close supervision of specialized personnel. The safety regulations regarding work in the conditions of ionising radiation exposure should be strictly complied with during the preparation and administration of a radiopharmaceutical.

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

After administration of PoltechMDP, you should:
- avoid any close contact with young children and pregnant women for the 24 hours following the injection,
- 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 your nuclear medicine doctor if you have any questions.

If you have been given more PoltechMDP than you should
An overdose is unlikely, because you will only receive a dose of product precisely controlled by the nuclear medicine doctor supervising the procedure. However in the case of an overdose your doctor may recommend that you drink plenty of fluids to remove the traces of radiopharmaceutical from your body.

Should you have any further questions on the use of PoltechMDP, please ask your doctor or the nuclear medicine doctor who supervises the procedure.

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects were reported after intravenous administration of PoltechMDP: headache, arthralgia, nusea, vomiting, lowered blood pressure, erythema or skin rash, itching, dermal irritation, oedema of the extremities, malaise, very rare: anaphylaxis.

This side effects are usually short-lasting, mild severe and its exact frequency cannot be estimated from the available data.

The administered radiopharmaceutical will deliver low amount of ionising radiation associated with the least risk of cancer and hereditary abnormalities. For diagnostic nuclear medicine investigations the current evidence suggests that these adverse reactions are expected to occur with a low probability.

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.
Adverse reactions may be reported to Marketing Authorisation Holder.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How PoltechMDP 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.

PoltechMDP 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.

6. Contents of the pack and other information

What PoltechMDP contains
- The active substance is methylenediphosphonic acid
- The other ingredients are stannous chloride dihydrate, ascorbic acid, nitrogen.

What PoltechMDP looks like and contents of the pack
Kit for radiopharmaceutical preparation.
White powder.
Product is delivered in 10 ml glass vials sealed with a rubber stopper and an aluminium cap packed in a cardboard boxes.

Pack sizes: 3 vials or 6 vials.
Each vial contains lyophilisate for solution for injection.

Marketing Authorisation Holder and Manufacturer
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For any more detailed information about this medicine, please contact your doctor or the local representative of the Marketing Authorisation Holder.

This leaflet was last revised in: 30.08.2016.

The complete SmPC of PoltechMDP is provided as a tear-off sectionat the end of the printed leaflet in the product package, with the objective to provide healthcare professionals with other additional scientific and practical information about the administration and use of this radiopharmaceutical.
Please refer to the SmPC.