1. NAME OF THE MEDICINAL PRODUCT
M Gupta 5 mg, powder for solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each vial contains 5 mg of medicinal substance. Sodium pertechnetate (99mTc) solution for injection must be used for preparation of the technetium-99m (99mTc) diagnostic agent.

The radiocolloid is not part of the kit.

Expiry: 2 years from the date of manufacture, see section 6.1.2.

3. PHARMACOLOGICAL FORM
Kit for radiopharmaceutical preparation.

For solution for injection:

Dried powder

To be reconstituted with sodium pertechnetate (99mTc) solution for injection (not included in this kit) before administration.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
This medicinal product is for diagnostic use only.

4.2 Posology and method of administration

Preparation

1. Radiochemical preparation:

- 370 - 740 MBq 99mTc-MDP for intravenous administration

- 18.7 - 37.4 MBq 99mTc-MDP for intravenous administration

The injection should be prepared by skilled personnel in a radiopharmacy.

The radiochemical preparation should be performed in the range of 3 - 6.0 GBq of 99mTc activity to be used in the course of a nuclear medicine examination, with the labelled content of one vial can be calculated from the activities for the examinations.

- 2.5 kg

- 2.0 kg

- 1.5 kg

- 1.0 kg

- 0.5 kg

- 0.25 kg

- 0.125 kg

- 0.0625 kg

- 0.03125 kg

The technetium-99m is a radioactive isotope with a half-life of 6.0 hours. The radionuclide has applications in medicine, especially in nuclear medicine.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.2.

- Pregnancy and lactation

- Children under 18 years of age except if the necessity and importance of obtaining the diagnostic information outweighs the risk associated with the radiation exposure.

- Pregnancy and lactation (see Section 4.4) except if the necessity and importance of obtaining the diagnostic information outweighs the risk associated with the radiation exposure.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacodynamic properties: Diagnostic radiopharmaceutical. ATC code: V06BA02 After intravenous administration, 99mTc-MDP — similar to other 99mTc-diphosphates (e.g., sodium pertechnetate). After intravenous administration, 99mTc-hydroxyethylidene 1,1-diphosphonate (99mTc-HEDP) is rapidly cleared from the blood and taken up largely by the bone system and almost negligibly by the liver. Most of the uptake is non-exchange and chemoisorption in the isonitrile matrix of the bone, in its inorganic hydroxyl phosphate (CaO(OH)PO4) (OH2) phosphate group on the surface of the bone matrix react with the free PO3, groups of MDP-coated osteoclasts resulting in lead loss. This process occurs in the healthy bone, but accumulation at sites where is active like the bone metastases. The process is not affected by the activity of osteoclasts. Therefore, bone lesions (primary tumours, metastases, fractures, radiodense bone) can be detected higher. The radiocolloid activity in the bones is higher than in the vascular system. The elimination of the hepatobiliary system is negligible. Significantly smaller quantity of the administered 99mTc-MDP binds to the proteins of the bloodstream (especially albumin), allowing an accurate recovery treatment of radiation overdose. The table contains absorbed radiation dose data in significant organs.

- Ovaries

- Muscles

- Liver

- Colon

- Bone

- Kidney

- Pharynx

- Oesophagus

- Lung

- Brain

- Skin

- Hair

- Eye

- Thymus

- Liver

- Adrenal glands

- Thyroid

- Eyes

- Testes

- Pancreas

- Contraceptives

6. SPECIFIC PRECAUTIONS FOR USE

6.1.4 Dosimetry

99mTc-MDP dose of a patient contains 370-740 MBq of activity. The table below shows the radiation doses absorbed by healthy subjects, based on the dose of the radiopharmaceutical and Tc51 phosphate administered. (Based on the ICRP 1989 recommendations).

- Future further advancement of the product is safe. The range of the 99mTc-MDP dose of a patient contains 370-740 MBq of activity. The table below shows the radiation doses absorbed by healthy subjects, based on the dose of the radiopharmaceutical and Tc51 phosphate administered. (Based on the ICRP 1989 recommendations).

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340 mBq for a healthy 70 kg body weight is 4.21 mSv of the effective dose. 740 MBq of 
Tc
radiopharmaceutical, active for the effective dose for the target organ (bone) is 46.62 mSv and 35.52 mSv
for the critical organ (bladder wall).

Radiotherapy physical properties of 99m
Tc
are as follows:

Physical half-life: 6 hours
Energy and intensity of the emitted gamma photons: 140 keV (10%) 
Secondary product of the reaction is \( \text{Tc}^{94m} \), which is produced during the short half-life of \( \text{Tc}^{99m} \) in quantity less than 0.1%.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

The radiopharmaceutical preparation

Remove the strip and put it in the upper part of the paper bag to access the vials.

The MDP kit never administers directly without preparing the labeling, only \( \text{Tc}^{99m} \) can be administered after preparation with sodium pertechnetate (\( \text{Tc}^{99m} \)) solution for injection Pk Ease.

Preparation procedure

Labelled product: The labelled product is prepared by beta decay via the next reaction:

\[ \text{Tc}^{99m} \text{MDP} \text{generator for labelling. Injection: MDP radioactive sterile diagnostic injection, prepared from MDP kit containing the labelled product and the administration of injection permitted only in departments of nuclear medicine.} \]

The product is a clear, colourless, tasteless, odorless solution for intravenous administration. After intravenous administration, \( \text{Tc}^{99m} \)-MDP is transported to the bones via the blood circulation. Hydroxyapatite, which is one component of bone, binds \( \text{Tc}^{99m} \)-MDP. This reaction enables the accumulation of the substance in the skeletal system and bone lesions become visible. After administration, a free fraction of the \( \text{Tc}^{99m} \) can be detected from the blood by gamma camera. The pictures taken by this camera show the distribution of the radioactive isotope in your body and organs time to time. The pictures can give your doctor valuable information about the structures and function of the organ helping this way to choose the best treatment.

When using \( \text{Tc}^{99m} \)-MDP injection, you receive a small amount of radioactive radiation. Nuclear medical specialist considered that the benefits of the examination outweighs the radiation exposure.

2. What you need to know before you use \( \text{Tc}^{99m} \)-MDP injection

Do not use MDP injection:

- if you are allergic (hypersensitive) to the active substance or any of the other ingredients of MDP;
- if you are pregnant;
- if you are breastfeeding;
- if your child is under 18 years of age, or if your doctor decides otherwise.

Warnings and precautions

Your doctor will advise you if you need any special precautions when using \( \text{Tc}^{99m} \)-MDP.

If you are given more than the usual dosage of \( \text{Tc}^{99m} \)-MDP you than needed.

The handling, use, and disposal of radiopharmaceuticals are strictly regulated. The \( \text{Tc}^{99m} \)-MDP injection can be used only in a hospital or in an institution that is authorized to prepare the labelled product. The product is only for intravenous administration. The doctor gives you instructions on any precautions that must be strictly observed. Since the radiopharmaceuticals are dangerous for the environment, anyone who handles the product, anyone who works in the vicinity of the product and anyone who deals with the disposal of the product must take special care for the safe use of this product and to keep yourself and your family informed of this.