IZOTOP

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

MDP 5 mg, powder for solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains 5 mg of medronic acid. Sodium pertechnetate (^{99m}Tc) solution for injection should be used for preparation of the technetium (^{99m}Tc) MDP diagnostic injection. The radionuclide is not part of the kit.
Excipients: For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Kit for radipharmaceutical preparation.
Powder for solution for injection.
Freeze-dried powder.
To be reconstituted with sodium pertechnetate (^{99m} Tc) 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.
Indication field:
Bone scintigraphy for diagnostic study. Use of the preparation is highly recommended for indications listed below:

- Primer bone tumours,
- Metastases of other tumours, e.g. prostate cancer, breast cancer, lung cancer,
- Osteomyelitis,
- Metabolic bone diseases,
- Paget's disease.

4.2 Posology and method of administration

Posology
Adults
370 - 740 MBq ^{99m}Tc MDP for intravenous administration.
The radiolabelling should be performed with such an activity of sodium pertechnetate (^{99m}Tc) solution to provide 370 - 740 MBq ^{99m}Tc activity dose for 70 kg average body weight at the time of application.
The radiolabelling should be performed in the range of 3.0 - 6.0 GBq of ^{99m}Tc activity to provide sufficient activity at the time of administration. Number of patients to be examined with the labelled content of one vial can be calculated from the activities recommended for the examinations.
Elderly population
The need for dosage adjustments in geriatric populations has not been systematically investigated. Decreased renal function (see below) and decreased osteogenesis in the elderly may affect the uptake, distribution, or elimination of technetium (^{99m}Tc) medronate injection.
Patients with renal and hepatic impairment
Careful consideration of the activity to be administered is required since an increased radiation exposure is possible in these patients.
Children and adolescents
For children and adolescents, the EANM recommends a baseline activity of 35 MBq for ^{99m}Tc-bisphosphonates (at least 40 MBq activity), that should be adjusted based on the class of the radiopharmaceutical (class B) and the weight of the child.

EANM practice guidelines for bone scintigraphy (2016)	Children						Adults
Body weight	3.5 kg	10 kg	20 kg	30 kg	40 kg	50 kg	
Activity (MBq)	40	95	170	240	310	375	300 – 740
Effective dose (mSv)	2.0	2.4	2.5	2.6	2.7	2.8	2.9 – 4.0

Method of administration
^{99m}Tc-MDP is administered intravenously to the patient. Bone scintigraphy, which can be whole body or targeted scan and SPECT scan, should be performed 2-4 hours after administration. Imaging with gamma camera or scanner should be performed after administration. For instructions on reconstitution of the medicinal product before administration, see section 12.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Under 18 years of age except if the necessity and importance of obtaining the diagnostic information outweights the risk associated with the radiation exposure.
- Pregnancy and lactation (See section 4.6) except if the necessity and importance of obtaining the diagnostic information outweights the risk associated with the radiation exposure.

The product must not be used if the patient does not provide an oral or written consent of being examined by using radionuclide.

4.4 Special warnings and precautions for use

When hypersensitivity or anaphylactic reactions occur, the use of the preparation should be discontinued immediately and, if necessary, intravenous therapy should be initiated. In the event of an emergency, the medication needed for immediate action and the necessary equipment for intubation and respiration must be available immediately.
Individual benefit/risk justification:
For each patient, the radiation exposure must be justifiable by the likely benefit. The activity administered should in any case be as low as reasonably achievable to obtain the required diagnostic information.
Paediatric population
The use of this product is contraindicated in the age of 18 years unless the importance of obtaining diagnostic information outweighs the risk of exposure to the radiation. In this case, a reduced amount of activity should be used (see section 4.2).
The use of this product in pregnant women and during lactation is contraindicated unless the importance of obtaining diagnostic information outweighs the risk of exposure (see section 4.6).
Patient preparation
The patient should be well hydrated before the start of the examination and urged to void as often as possible during the first hours after the study in order to reduce radiation.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Women of childbearing potential
The intended exposure to diagnostic radiation should be limited as far as possible to the first 10 days of the ovulation cycle. If a radioactive medicinal product is to be used to treat women of childbearing potential, the possibility of pregnancy should always be considered. Any woman who has missed a period should be assumed to be pregnant. If in doubt about her potential pregnancy it is important to keep radiation exposure as low as resonable to determine the desired clinical information. In all such cases, should be considered to the use alternative techniques not using ionising radiation.
Pregnancy
Radionuclide procedures carried out on pregnant women also involve radiation dose to the fetus. Only essential investigations should therefore be carried out during pregnancy, when the likely benefit far exceeds the risk incurred by the mother and fetus.
Breastfeeding
Before administering radiopharmaceuticals to a mother who is breastfeeding consideration should be given to the possibility of delaying the administration of radionuclide until the mother has ceased breastfeeding, and to what is the most appropriate choice of radiopharmaceuticals, bearing in mind the secretion of activity in breast milk. If the administration is considered necessary, breastfeeding should be interrupted for 12 hours and the expressed feeds discarded. Breastfeeding can be continued when the activity measured in breast milk does not represent a radiation dose exceeding 1 mSv for the child.

4.7 Effects on ability to drive and use machines

MDP has no or negligible influence on the ability to drive and use machines. In occurrence of unexpected adverse reactions driving and/or working with machines should be reconsidered.

4.8 Undesirable effects

Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. The recommended activity is administered these adverse reactions are expected to occur with a low probability. Radiation dose (EDE) during the most nuclear diagnostic examination is less than 20 mSv.
Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system one of the contacts (In Hungary: www.ogyei.gov.hu).

4.9 Overdose

No case of overdose has been reported. In the unlikely event of overdose the vital functions of the patient should be supported. The radiation overdose can be reduced by forced diuresis and frequent bladder voiding.
Administration of higher activities than prescribed is unnecessary and must be avoided in order not to cause excess of absorbed radiation dose to the patient and his/her environment. In case of incidental overdose, the effectively administered activity of ^{99m}Tc must be determined (in MBq) and the actual absorbed radiation dose (for the organs and the whole body) must be calculated by using the data of the dosimetric table of Chapter 11.
Based on the values obtained, it is necessary to decide whether the patient should undergo a recovery treatment of radiation overdose. The table contains absorbed radiation dose data in μGy in case of intravenous administration of 1 MBq of ^{99m}Tc-MDP. Multiply these specific absorbed radiation dose data by the effectively administered activity in MBq to obtain the required absorbed radiation dose data in μGy.
If the whole radiolabelled contents of a vial are injected into a single patient by mistake or staff error, this is the administration of 5 mg of ^{99m}Tc-MDP.
An intravenous acute toxicity study in mice showed no clinical signs of up to 9 mg / kg. If a single patient received of the whole amount of the MDP vial by mistake, it represents 0.0714 mg/kg of bodyweight level calculated on 70 kg average bodyweight. This is equivalent to 0.8% of the no observed effect level. Thus, no toxic effects are expected in case of overdose.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Diagnostic radiopharmaceutical, ATC code: V09BA02
After intravenous administration, ^{99m}Tc-MDP - similarly to other ^{99m}Tc diphosphonates (eg. hydroxymethylene diphosphonate, 1-hydroxyethylidene 1,1-diphosphonate) is rapidly cleared from the blood and taken up largely by the bone system and almost negligibly by the soft tissues. Mechanisms of the uptake are ion exchange and chemisorption in the inorganic matrix of the bone, in ionic hydroxyapatite ($Ca_{10}(PO_4)_6(OH)_2$). Phosphate groups on the surface of the bone matrix react with the free PO_3H_2 groups of MDP-co-ordinated technetium to ion-exchange reactions resulting in ^{99m}Tc activity binding to the bone matrix. This process occurs in the healthy bone, but accumulation is higher at sites which are characterised by the increased bloodstream and increased bone generating activity (osteoblast function). Therefore, bone lesions (primary tumors, metastases, fissure, fractures, inflammations) can be found higher ^{99m}Tc radioactivity, allowing for excellent imaging. Significantly smaller quantity of the administered ^{99m}Tc-MDP binds to the proteins of the blood plasma, resulting a low whole body background. ^{99m}Tc-MDP unbound in the bone marrow is excreted in the urine, the elimination of the hepatobiliary system is negligible. Generally 50 % of the administered dose is accumulated in the bones and in healthy humans not more than 31%. However, at the site of bone metastases, 40% of the administered activity accumulates in metastasis, so the metastases are highlighted in the bone system image significantly. Same uptake can be observed in fractures, inflammations, hyperparathyroidism and osteoporosis.General principle in the isotope diagnostic imaging is that the radioactive tracer material should not affect the tracer system, ie the physiological processes in the human body or the effect on bone formation should be negligible. This condition is met when the prescribed preparation is given.

5.2 Pharmacokinetic properties

Intravenously administered ^{99m}Tc-MDP is cleared from the blood in three steps:

1. rapid phase, $T_{1/2}$ = 3.5 min,
2. moderate phase, $T_{1/2}$ = 27 min,
3. slow phase, $T_{1/2}$ = 144 min.

In the rapid phase, ^{99m}Tc-MDP is cleared from the blood to the extravascular area. The moderate phase is equivalent to the bone uptake. In the slow phase, the dissociation of ^{99m}Tc-MDP bounded to the plasma proteins in the blood occurs. The maximum bone uptake occurs 1-2 hours after administration and remains unchanged for about 72 hours.
^{99m}Tc-MDP is excreted via the urine. The highest activity in the kidneys appears at 20 minutes after administration. In case of normal renal function, 32% of the total administered activity is filtered glomerularly. 47% of the glomerularly filtered portion is present in the urine within 2 hours, and 60% in 6 hours after administration. Activity in the liver and in the intestines is negligible.

5.3 Preclinical safety data

Acute toxicity studies on mice showed no clinical symptoms, if less than 9 mg/kg of bodyweight is administered. If the administration complies with the recommendations, quantity of ^{99m}Tc-MDP administered to one patient is minimum 0.3 mg and maximum 1.23 mg. If the whole content of the MDP vial is administered to one patient by mistake, 5 mg of MDP is introduced in the body which represents 0.0714 mg/kg of bodyweight calculated on 70 kg average bodyweight. This is equivalent to 0.8 % of the no observed effect level. Thus, the administration of the preparation can be considered safe.

Further advantage of the product is that the range of 3 - 6 GBq activity of ^{99m}Tc pertechnetate does not affect the radiochemical purity of the preparation and the total quantity of radiochemical impurities is always less than 5%. The kit can be considered safe in its radiolabelling.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Stannous chloride dihydrate, ascorbic acid, urea

6.2 Incompatibilities

One component of MDP kit is stannous chloride is a reducing agent converts the free pertechnetate (+7 oxidation state) to +4 oxidation state, in which technetium readily forms complex with MDP. Thus the content of the vials is incompatible with moisture and oxidising agents (chemical oxidation agents or oxygen of the air). Alkaline media facilitate the oxidation of Sn(II) before the labelling reaction, this is why the product is incompatible with bases. It is recommended to remove the closure of the vials just right before the radiolabelling according to the instructions detailed in Section 12.

6.3 Shelf life

Kit: 12 months (from the manufacturing date)
The radiolabelled injection: after reconstitution and radiolabelling 6 hours

6.4 Special precautions for storage

Kit: Store in refrigerator (2°C - 8°C)
The radiolabelled injection: Do not store over 25°C. Comply with the regulations for radiation safety.

6.5 Nature and contents of container

Freeze-dried powder in the vial closed with rubber stopper and tear-off kombicap aluminium and plastic. One box contains Six vials in one box.
Contents of container
6 vials, one Summary Of Product Characteristic and Patient Information Leaflet and six labels with "radioactive material" sign.

6.6 Special precautions for disposal and other handling

General warnings
Radiopharmaceuticals should be received, used and administered only by authorized persons in designated clinical settings. Their receipt, storage, use, transfer and disposal are subject to the regulations and/or appropriate licenses of the local competent official organization. Radiopharmaceuticals should be prepared in a manner which satisfies both radiation safety and pharmaceutical quality requirements. Appropriate aseptic precautions should be taken.
Contents of the vial are intended only for use in the preparation of ^{99m}Tc-MDP injections and are not to be administered directly to the patient without first undergoing the preparative procedure.
For instructions on reconstitution of the medicinal product before administration, see section 12. If at any time in the preparation of this product the integrity of the vial is compromised it should not be used.
Administration procedures should be carried out in a way to minimize risk of contamination of the medicinal product and irradiation of the operators. Adequate shielding is mandatory.
The content of the kit before extemporary preparation is not radioactive. However, after sodium pertechnetate (^{99m}Tc) solution for injection Ph. Eur. is added, adequate shielding of the final preparation must be maintained.
The administration of radiopharmaceuticals creates risks for other persons from external radiation or contamination from spill of urine, vomiting etc. Radiation protection precautions in accordance with national regulations must therefore be taken.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.
Classification: Group II / 3
In accordance with CLIV 1997 on Health Care, (I), which may be used under the conditions provided by providers of outpatient care or inpatient services provided by the outpatient clinic under section 3 (a) of the Act requirements.

7. MARKETING AUTHORISATION HOLDER

Institute Of Isotopes Co. Ltd.
Addresse: 1121 Budapest, Konkoly Thege Miklós str. 29-33.
1535 Budapest, P.O.B. 851.
Tel.: 36 1 391 0859 3910860
Fax: 36 1 395 9070
E-mail: commerce@izotop.hu, radiopharmacy@izotop.hu

8. MARKETING AUTHORISATION NUMBER(S)

OGYI-T-9702/01

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19 May 1992
Date of latest renewal: 17 December 2009

10. DATE OF REVISION OF THE TEXT

24 July 2017

11. DOSIMETRY

^{99m}Tc-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 [^{99m} Tc] phosphate and [^{99m} Tc] phosphonate administered. (Based on the 80th ICRP International).

Organ	**Absorbed radiation doses: 99mTc-phosphate and phosphonate (mGy/MBq)**				
	Adult	**15 years**	**10 years**	**5 years**	**1 year**
Adrenals	0.0021	0.0027	0.0039	0.0058	0.011
Bladder wall	0.048	0.060	0.088	0.073	0.13
Bone surfaces	0.063	0.082	0.13	0.22	0.53
Brain	0.0017	0.0021	0.0028	0.0043	0.0061
Breast	0.00071	0.00089	0.0014	0.0022	0.0042
Gall Bladder	0.0014	0.0019	0.0035	0.0042	0.0067
Stomach wall	0.0012	0.0015	0.0025	0.0035	0.0066
Small intestine	0.0023	0.0029	0.0044	0.0053	0.0095
Colon	0.0027	0.0034	0.0053	0.0061	0.011
Upper large intestine	0.0019	0.0024	0.0039	0.0051	0.0089
Lower large intestine	0.0038	0.0047	0.0072	0.0075	0.013
Heart	0.0012	0.0016	0.0023	0.0034	0.0060
Kidneys	0.0073	0.0088	0.012	0.018	0.032
Liver	0.0012	0.0016	0.0025	0.0036	0.0066
Lungs	0.0013	0.0016	0.0024	0.0036	0.0068
Muscles	0.0019	0.0023	0.0034	0.0044	0.0079
Oesophagus	0.0010	0.0013	0.0019	0.0030	0.0053
Ovaries	0.0036	0.0046	0.0066	0.0070	0.012
Pancreas	0.0016	0.0020	0.0031	0.0045	0.0082

Organ	Absorbed radiation doses: 99mTc-phosphate and phosphonate (mGy/MBq)				
	Adult	**15 years**	**10 years**	**5 years**	**1 year**
Red Marrow	0.0092	0.010	0.017	0.033	0.067
Skin	0.0010	0.0013	0.0020	0.0029	0.0055
Spleen	0.0014	0.0018	0.0028	0.0045	0.0079
Testes	0.0024	0.0033	0.0055	0.0058	0.0011
Thymus	0.0010	0.0013	0.0019	0.0030	0.0053
Thyroid	0.0013	0.0016	0.0023	0.0035	0.0056
Uterus	0.0063	0.0076	0.012	0.011	0.018
Remaining organ	0.0019	0.0023	0.0034	0.0045	0.0079
Effektive doses (mSv/MBq)**:**	**0.0057**	**0.007**	**0.011**	**0.014**	**0.027**

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

Radiation physical properties of ^{99m}Tc-MDP are as follows:

Physical half-life	6 hours	
Energy and intensity of the emitted gamma photons	140 keV	100 %
Energy and intensity of the emitted beta particles	_	_

During the decay ^{99}Tc is produced.
^{99m}Tc isotope is produced in the ^{99}Mo generator by β-decay via the next reaction:

$$^{99}Mo \xrightarrow{\beta} {}^{99m}Tc$$

Secondary product of the reaction is ^{99}Tc radioisotope, which is produced owing to the short half-life of ^{99m}Tc in quantity less than 0.1%.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

The radiopharmaceutical preparation
Remove the shringing foil and lift up the upper part of the paper box to access the vials.
The MDP kit never adminiter directly without performing the labelling, only ^{99m}Tc-MDP injection can be administered after preparation with sodium pertechnetate (^{99m} Tc) solution for injection Ph Eur.
^{99m}Tc-MDP solution contains radioactive isotope. For handling, shipping and storage of this product the rules and regulations referring to the radioactive materials should be observed.
Labelling procedure
The preparation must be performed under aseptoc condition. Place the vial which contains the freeze-dried powder in a small lead container with a wall thickness of 3 mm. Under aseptic circumstances inject 3 - 6 GBq of sterile sodium pertechnetate into the vial through the rubber stopper with a sterile syringe. Volume of the sodium pertechnetate solution should be not less than 2 ml and not more than 5 ml. If it is necessary, use saline for dilution. Shake well. Incubate the vial at room temperature for 15 minutes. Now the labelled substance (^{99m}Tc-MDP) can be intravenously administered. pH of the labelled solution is in the range of pH=5.0 - 7.0.
The labelled solution can be used in 6 hours. During this period the percentage of radiochemical impurities should not be more than 5%.
Control of the drug product
Radiochemical purity of the Injection: Thin layer chromatography Ph. Eur. 2.2.27
Preparation of injection: use the eluate of a ^{99}Mo/^{99m}Tc generator for labelling. Inject the ^{99m}Tc eluate which has an activity between 0.8 - 1.6 GBq – in no more than 3 ml volume – into a vial using a using disposable sterile syringe and needle without removing its cap. Shake it regularly and allow 15 minutes for the complexation reaction to finish. Label one vial and develop three parallel chromatograms.
Test "A" (determination of the ratio of reduced, hydrolyzed ^{99m}Tc): prepare 3 pieces of 1.5cm×15cm strips from ITLC-SG chromatographic layer. Mark the start point from 1.5 cm from the end of the strip. Using a pipette apply 5 µl of labelled product to the start point. Don't let the spot dry in air. Develop the chromatograms immediately in 136 g/L (1M) sodium-acetate as eluent till the front distance of 10 cm has reached. After removing the strips from the tank, dry them in air and impregnate with 5% polystyrene solution. After the polystyrene coating has dried, record the chromatogram by gamma scanner.
Expected R_f values are:
Reduced, hydrolyzed ^{99m}Tc 0.0 – 0.1
Labelled complex and free $^{99m}TcO_4^-$ 0.9 – 1.0
Test "B" (Determination of the ratio of free pertechnetate): prepare 3 pieces of 1.5cm×15cm strips from ITLC-SG chromatographic layer. Mark the start point from 1.5 cm from the end of the strip. Using a pipette apply 5 µl of labelled product to the start point. Let the spot dry in air. After the spot has dried, develop the chromatograms in methyl ethyl ketone solution, till the front distance of 10 cm has reached. After removing the strips from the tank, let them dry in air and impregnate them with 5% polystyrene solution. After the polystyrene coating has dried, record the chromatogram by gamma scanner.
Expected R_f values are:
Labelled complex and reduced, hydrolyzed ^{99m}Tc 0.0 – 0.1
Free $^{99m}TcO_4^-$ 0.9 – 1.0
Calculation: Radiochemical purity: 100 – (A+B
Specification: The radiochemical purity (relative amount of labelled complex) is not less than 95%.
Any unused product or waste material should be disposed of in accordance with local requirements.

Package leaflet: Information for the user
MDP 5 mg powder for solution for injection
Medronic acid

Read all of this leaflet carefully before you using 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.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What ^{99m}Tc-MDP injection is and what it is used for
2. What you need to know before you use ^{99m}Tc-MDP injection
3. How to use ^{99m}Tc-MDP injection
4. Possible side effects
5. How to store ^{99m}Tc-MDP injection
6. Contents of the pack and other information

1. What ^{99m}Tc-MDP is and what it is used for
This medicinal product is a radiopharmacetucal for diagnostic use conatining radiactive isotope . ^{99m}Tc-MDP radioactive sterile didnostic injection, prepared from MDP kit containing ^{99m}Tc isotope and the administration of inection permitted only in departments of nuclear medicines.
^{99m}Tc-MDP is a clourless solution for intravenous administration. After intravenous administration, ^{99m}Tc-MDP is transported to the bones via the blood circulation. Hydroxyapatite, which is one component of the bones, bounds ^{99m}Tc-MDP. This reaction enables the accumulation of the substance in the skeletal system and bone lesions become visible. After administration of the injection, you have to drink approximately 1 L of water.
As the medicine contains gamma-radiator radioactive isotope, it can be detected from outside the body using gamma cameras. 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 structure and function of the organ helping this way to choose the best treatment.
When using ^{99m}Tc MDP injection, you receive a small amount of radioactive radiation. Nuclear medical specialist considered that the benefits of the esamination outweighs the radiation exposure.

2. What you need to know before you use ^{99m}Tc MDP injection
Do not use MDP
- if you are allergic (hypersensitive) to the active substance or any of the other ingredients of MDP,
- if you are pregnant or breastfeeding, except if your doctor decides otherwise,
- if you are under 18 years of age, except if your doctor decides otherwise.
-

Warnings and precautions
Inform the nuclear medicine specialist if any of the following apply to you:
- if you are pregnant or think you may be pregnant,
- if you are breastfeeding,
When using 99mTc-MDP injection, you are given a small amount of radioactive radiation. Although this effect is less than in some X-rays, your doctor will always take into account potential risks and benefits.
If you have any doubt, it is important to consult your doctor before receiving the product.
Make sure you carry out the doctor's instructions both before and after the examination in order to avoid radioactive exposure of other people and the radioactive contamination of the environment. The radioactive isotope is excreted in the urine, faeces, sweat and other secretions temporarily contaminating the environment this way.

Before administration ^{99m}Tc-MDP injection
Before administration drink plenty of water and to be well hydrated before the start of the examination in order to urinate as often as possible during the first hours after the study.

Children and adolescent
Tell your nuclear medicine specialist if you are under 18 years of age.
^{99m}Tc-MDP injection is not recommended for children and adolescents under the age of 18, but in this case the physician must decide whether radioisotope examination is absolutely necessary.

Using other medicines
Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. No interactions with other medicines are known.

^{99m}Tc-MDP with food and drink
Any food and drink can be consumed.

Pregnancy and breastfeeding
Be sure to tell the nuclear medicine specialist before administarting ^{99m}Tc-MDP injection if you are pregnant, if you miss a period or if you are breastfeeding. If you are unsure of anything, be sure to talk to the nuclear medicine specialist.
Pregnancy
Examination of radioactive radiation on pregnant women is a risk to the fetus as well. During pregnancy, therefore, only indispensable examinations can be carried out when the expected benefit outweighs the risk to the mother and the child.
Breastfeeding
Since radioactivity can be absorbed into breast milk the consideration should be given to the possibility of delaying the administration of radionuclide until the mother has ceased breastfeeding. If you are breastfeeding and the doctor decides to perform the examination, the breastfeeding should be discontinued for as long as it is recommended by the doctor. During that time, pour out breast milk until radioactivity is clearing from your body. At the time the infant should be nourished artificially. Breastfeeding can be restarted when the radiation dose in the milk is not greater than 1 mSv for the child. The doctor must decide on the time for restarting.

Driving and using machines
^{99m}Tc-MDP has no or negligible influence on the ability to drive and use machines

MDP 5 mg powder for solution for injection contains stannous chloride dihydrate, ascorbic acid, urea

3. How to use ^{99m}Tc-MDP
There are strict laws on the use, handling and disposal of radiopharmaceutical products. ^{99m}Tc-MDP 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. The Nuclear medicine doctor supervising the procedure will decide on the quantity of the ^{99m}Tc-MDP injection to be used in your case. It will be the smallest quantity necessary to get the desired information. The quantity to be administered usually recommended for an adult ranges from 370 to 740 MBq (MBq = Mega Becquerel, the unit used to express radioactivity).
^{99m}Tc-MDP injection is prepared at site of use (clinical, hospitalized isotope laboratory) by mixing MDP and radioactive ^{99m}Tc pertechnetate solution. It is used as an intravenous injection.

Use in children and adolescents
^{99m}Tc-MDP injection is not recommended for children and adolescents under the age of 18, but the physician will decide ether radioisotope examination is absolutely necessary. In children and adolescents, if the physician decides to use, amount to be administered is adjusted to the body weight.

Duration of the examination
Your nuclear medicine specialist will inform you of the expected duration.

After administration of ^{99m}Tc-MDP injection
Drink large amounts of fluid and urge to void as often as possible before and after treatment. This prevents the radioactive substance from accumulating in the bladder.
Your doctor will advise you if you need any special precautions when using the ^{99m}Tc-MDP.

If you are given more ^{99m}Tc-MDP than you need
The use, handling and destruction of radioactive materials are strictly regulated. The ^{99m}Tc-MDP injection can always be used only in a hospital or in an appropriate facility. Only persons who have specialized in this field and who have received appropriate training in the handling of radioactive materials can use and administer the injection. These people give you instructions on any precautions that must be strictly observed.
Since the ^{99m}Tc-MDP solution is injected under strictly controlled conditions by a physician, any overdose probability is small. If overdose occurs, then you will be treated appropriately. The doctor advises you to drink plenty of fluid to speed up the clearance of the drug from your body. Take care to avoid contamination with radioactive substances that are to be discharged, and follow your doctor's instructions carefully. The radioactive ^{99m}Tc-MDP is temporarily in the body and leaving it, radioactivity decreasing naturally.
If you have any further questions on the use of this product, please contact your Nuclear Medicine practitioner.

4. Possible side effects
Like all medicines, this medicine may cause side effects, although not everybody gets them. Ionizing radiation can cause cancer and / or hereditary illnesses. Due to the amount of radioactivity used during the examination, their probability is low.
Your doctor chooses the activity required for your examination / treatment to minimize the radiation dose and obtaining the desired diagnostic or therapeutic results. If you have any problems or doubts, consult your nuclear medicine specialist.
It is important for your doctor to report any other side effects or unusual illness.

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system one of the contacts (In Hungary: www.ogyei.gov.hu). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store ^{99m}Tc-MDP injection
You do not have to store the medicine. This medicine is stored under proper condition supervised by a specialist. Radioactive medicines are stored in accordance with national regulations for radioactive materials. Hospital staff are responsible for the proper storage of the product and not to give you an expired preparation.
The following information is for healthcare professionals only.
Keep out of the reach of children, unauthorized persons, use and handling.
Kit (MDP 5 mg powder for solution for injection): Store in a refrigerator (2 °C - 8 °C).
The radiolabelled preparation, ^{99m}Tc-MDP injection: Do not store over 25 °C, and store in compliance with radiation protection rules. The preparation should be used within 6 hours of the date of radiolabelling.
Do not use after the expiry date which is stated on the pack. The expiry date refers to the last day of the specified month.

6. Contents of the pack and other information
What MDP 5 mg powder for solution for injection contains
- The active substance: 5.0 mg medronic acid
- The other ingredients: Stannous chloride dihydrate, ascorbic acid, urea

The dr*ug substance of the radiolabelled MDP injection: ^{99m}Tc-MDP.*

What MDP 5mg looks like and contents of the pack
Description: Freeze-dried powder.
Before administration of injection to be dissolved with sodium pertechnetate (^{99m} Tc) solution for injection (not included in this kit).
Freeze-dried powder in the vial closed with rubber stopper and tear-off kombicap aluminium and plastic. Six vials in one box and six labels with "radioactive material" sign.

Marketing Authorisation Holder and Manufacturer
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