SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

DMSA 1.5 mg powder for solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains 1.5 mg of dimercaptosuccinic acid (DMSA).
Sodium pertechnetate (^{99m}Tc) solution for injection should be used for preparation of the technetium (^{99m}Tc) DMSA 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 radiopharmaceutical preparation.
Powder for solution for injection.
Freeze-dried white powder (lyophilisate).
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: Isotope diagnostics.
After radiolabelling with sodium pertechnetate (^{99m}Tc) solution the ^{99m}Tc-DMSA obtained is indicated:

- Kidney scintigraphy, static kidney imaging, localisation of the kidneys with imaging.
- Determination of the functional mass of the kidney.
- Determination of the relative function ratio (percentage) of the left and right kidneys.

4.2 Posology and method of administration

Posology

Adults
111-185 MBq ^{99m}Tc-DMSA for intravenous administration.
Elderly population
Dosing recommendations for older patients are the same as adults.

Pediatric population
The use in children and adolescents has to be considered carefully, based upon clinical needs and assessing the risk/benefit ratio in this patient group.
For paediatric examination (see Chapter 4.3.) use Webster's equation to determine the activity to be administered:

$$A_{child} = \frac{\left[(N+1)\cdot A_{Adult}\right]}{N+7}$$

where N: age of the child [year]
A_{child}, A_{adult}: activity [MBq]

Method of administration
^{99m}Tc-DMSA obtained in one labelling reaction can be divided to 3-6 doses. Label content of one vial of DMSA kit by using 1.0-1.8 GBq of [^{99m}Tc] pertechnetate activity.
^{99m}Tc-pertechnetate activity for labelling must be chosen so that individual patient dose should be 111-185 MBq at the time of the investigation.

Method of examination
The patient receives ^{99m}Tc-DMSA as intravenous injection. In case of static imaging and kidney scintigraphy it is recommended to take images 1-3 hours after administration. In case of functional test the time-dependence of accumulation after administration can be measured.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients (listed in section 6.1) 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.
- Under 18 years of age (See section 4.2) except if the necessity and importance of obtaining the diagnostic information outweights the risk associated with the radiation exposure.

4.4 Special warnings and precautions for use

Potential for hypersensitivity or anaphylactic reactions
If hypersensitivity or anaphylactic reactions occur, the administration of the medicinal product must be discontinued immediately and intravenous treatment initiated, if necessary. To enable immediate action in emergencies, the necessary medicinal products and equipment such as endotracheal tube and ventilator must be immediately available.

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
Under 18 years of age except if the necessity and importance of obtaining the diagnostic information outweights the risk associated with the radiation exposure.
For information on the use in paediatric population, see section 4.2. Careful consideration of the indication is required since the effective dose per MBq is higher than in adults.

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.

Specific warnings
The labelled product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially "sodium-free".

4.5 Interaction with other medicinal products and other forms of interaction

No interactions are known.

4.6 Fertility, pregnancy and lactation

Women of childbearing potential
When an administration of radiopharmaceuticals to a woman of childbearing potential is intended, it is important to determine whether or not she is pregnant. Any woman who has missed a period should be assumed to be pregnant until proven otherwise. If in doubt about her potential pregnancy (if the woman has missed a period, if the period is very irregular, etc.), alternative techniques not using ionising radiation (if there are any) should be offered to the patient.

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
The ^{99m}Tc is secreted in breast milk.
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

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

4.8 Undesirable effects

Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. However these effects are hardly expected regarding the applied amount of activity.
Adverse event and reactions have not been reported ever since the authorization of the product (1989) not registered in the literature. Considering the number of the examinations carried out since, no adverse reactions are expected (frequency lower than 1/10000).

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.
The ^{99m}Tc-DMSA should be used and administered only by authorised persons in clinical departments. The potential for pharmacological overdose is negligible. In case of incidental overdose be ready to provide life support. Radiation dose to the body can be reduced by increased and frequent diuresis.
Administration of higher activities than prescribed is unnecessary and must be avoided in order to avoid the excess absorbed radiation dose of 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 must be calculated by using the data of the dosimetric table of Chapter 11. Necessity and method of further treatment should be concluded based on these results.
The table of Chapter 11 contains absorbed radiation dose data in μGy in case of intravenous administration of 1 MBq of ^{99m}Tc-DMSA. Multiply these specific absorbed radiation dose data by the effectively administered activity (in MBq) to obtain the required absorbed radiation dose data in μGy.
Quantity of ^{99m}Tc-DMSA administered to one patient is not less than 0.25 mg and not more than 0.50 mg if administration is complying with the recommendations. If the whole content of the vial containing the labelled substance is administered to one patient by mistake 1.5 mg of ^{99m}Tc-DMSA is introduced in the body.
Acute toxicity studies on mice showed no clinical symptoms if less than 0.43 mg/kg of bodyweight is administered. If the whole content of the vial containing the labelled substance is administered to one patient by mistake, it represents 0.0214 mg/kg of bodyweight level (calculated on 70 kg average bodyweight). This is equivalent to 5% 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: V09CA02
The structure of DMSA-complex administered to the body is [^{99m}Tc-$(DMSA)_2$], i.e. it is a biscomplex, of which 75% binds to the plasma proteins of the blood. Plasma-binding highly depends on the pH value of the product, at pH=3 binding is 90%, at pH=7 it is 50%.
[^{99m}Tc-$(DMSA)_2$] bounded to plasma proteins is taken up by the kidneys, it binds to receptors containing free -SH groups of the tubules, especially the proximal tubules. One DMSA ligand of [^{99m}Tc-$(DMSA)_2$] biscomplex is substituted by a –SH group of the receptor while one DMSA is released and the [^{99m}Tc-(DMSA)-receptor] complex is formed. The released DMSA is excreted via the urine. This mechanism allows the binding of not more than 0.1 mg of DMSA per kg of bodyweight.
With this mechanism maximum 0.1 mg DMSA can be bound per kg bodyweight.
Since the proximal tubules are situated in the cortex of the kidneys imaging is performed by visualising the cortex itself. 40-50% of the injected activity appears in the kidney cortex and approximately 3% in the liver. In case of patient with impaired kidney function this ratio decreases and the radioactivity of the liver increases significantly.
Finally, ^{99m}Tc-(DMSA) bound in the kidneys is excreted via urine.

5.2 Pharmacokinetic properties

After intravenous administration ^{99m}Tc-DMSA leaves the bloodstream in three parallel processes which can be described by three-compartmental exponential curve. The effective half-life is approximately 1 hour. Most of the activity leaves the bloodstream during the first two phases ($T_{1/2}$(I)=40 min and $T_{1/2}$(II)=120 min).
1 hour after administration 25-35% of ^{99m}Tc-DMSA activity is localised in the kidneys, while after 3 hours 40-50%. Simultaneously, 25% of the administered activity is excreted via the urine during the first hour. After 6 hours the excretion via urine increases.

5.3 Preclinical safety data

Acute toxicity study on mice showed no clinical symptoms up to 0.43 mg/kg of body weight. Quantity of ^{99m}Tc-DMSA, if administration is complying with the recommendations, is not less than 0.25 mg and not more than 0.5 mg. Calculated on an average 70 kg of bodyweight the smallest and the greatest quantities are equivalent to 0.8 and 1.6 % of the no observed effect level, respectively. Thus, the use of the product is considered safe.
Further advantage of the product is that radiochemical purity of the preparation is not affected by the activity of [^{99m}Tc]pertechnetate in the range of 1.0-1.8 GBq. Quantity of radiochemical impurities ([^{99m}Tc]pertechnetate ion) is always less than 2%, therefore the kit is safe from the point of view of labelling.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Stannous chloride dehydrate, ascorbic acid, calcium-gluconate.

6.2 Incompatibilities

For preparation of ^{99m}Tc-DMSA only ^{99m}Tc-pertechnetate- and physiological saline solution can be used (See section 12). The DMSA kit is incompatible with other materials.
Stannous chloride component of DMSA kit is a reducing agent. It reduces free pertechnetate from (+7) oxidation state to (+4) oxidation state, in which technetium readily forms complex with DMSA. It is important to keep away the content of the vials from moisture and oxidising agents, for example 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. As a result of these incompatibilities it is recommended to remove the closure of the closed injection vials just before the radiolabelling according to the instructions detailed in Section 12.

6.3 Shelf life

Kit: 24 month (from the date of the manufacture).
The radiolabelled injection: after reconstitution and radiolabelling it must be used within 8 hours.

6.4 Special precautions for storage

Kit: Store in refrigerator (2°C -8°C). Keep the bottle in the outer carton in order to protect from light.
The radiolabelled injection: Do not store ^{99m}Tc-DMSA injection above 25°C, protected from light. Storage of the radiolabelled injection should be in accordance with national regulation on radioactive materials.

6.5 Nature and contents of container

Sterile, type I, 6 ml (colourless, 6R type) injection vial; with winered (halobutyl) rubber stopper, with green, flip-off plastic shield with rolled aluminium cap.
Multidose vial.
One box contains six vials with powder, 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
The content of the kit before extemporary preparation is not radioactive. However, after sodium pertechnetate (^{99m}Tc) solution for injection is added, adequate shielding of the final preparation must be maintained.
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-DMSA 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.
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 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 1 392 2577; 395 9081 Fax: 36 1 395 9247; 392 2575
E-mail: radiopharmacy@izotop.hu

8. MARKETING AUTHORISATION NUMBER(S)

OGYI-T-9245/01

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

09 February 1989 / 17 December 2009

10. DATE OF REVISION OF THE TEXT

10/2018
This Summary of Product Characteristics was translated by the manufacturer based on the original Hungarian document, authorized by the Hungarian National Institute of Pharmacy on 10.2018.

11. DOSIMETRY

Technetium (^{99m}Tc) is produced by means of a (^{99}Mo/^{99m}Tc) radionuclide generator and decays with the emission of gamma radiation with an energy of 140 keV and a half-life of 6.02 hours to technetium (^{99}Tc) which, in view of its long half-life of 2.13 x 10^5 years, can be regarded as quasi stable.
Individual patient dose is 111-185 MBq. Estimated absorbed dose values of 1 MBq of the injection for an average body weight of 70 kg are given in the table below.

Organ	**Absorbed dose [µGy / MBq]**
Kidney cortex	205.0
Whole kidney	167.0
Urinary bladder	75.0
Liver	5.4
Ovaries	5.9
Whole body	4.3

Radiation physical properties

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

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

If at any time in the preparation of this product the integrity of the vial is compromised it should not be used.
Appropriate aseptic precautions should be taken.
Method of preparation
Remove the protective foil and lift up the upper part of the paper box to access the vials.
DMSA kit can only be administered to patient after labelling with ^{99m}Tc. Never administer DMSA kit without performing the labelling.
^{99m}Tc-DMSA injection 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:
Place the vial containing the freeze-dried powder in a small lead container with a wall thickness of 3 mm. Under aseptic circumstances inject 1.0-1.8 GBq of sterile sodium pertechnetate in no more than 3 ml into the vial through the rubber stopper with a sterile syringe. After 15 min reaction time measure the total activity of solution and the defined and measured patient dose of ^{99m}Tc-DMSA injection can be administered intravenously.
pH of the labelled solution is in the range of pH=2.3-3.5.
Use the labelled solution within 8 hours. During this period the percentage of radiochemical impurities ([^{99m}Tc]pertechnetate ion) should not be more than 2%.

Quality control
Radiochemical purity of the Injection (Ph. Eur. 0643).
Thin Layer Chromatography
Labelling: use the eluate of ^{99}Mo/^{99m}Tc generator. Place the vial containing DMSA in a small lead container with a wall thickness of 3 mm. Inject 1.0-1.8 GBq of steril ^{99m}Tc eluate in no more than 3 ml into the vial through the rubber stopper with a sterile syringe. Shake it regularly and allow 10-15 minutes for the complexation reaction to finish. Label one vial at a test and develop three parallel chromatograms.
Development of chromatograms: prepare 3 pieces of 1.5cm×15cm strips from ITLC-SG chromatographic layer, which has previously been heated at 110°C temperature for 10 minutes. Mark the start point from 1.5 cm from the end of the strip. Using a pipette apply 5 µl of labelled complex solution to the start point. Don't let the spot dry in air. After the spot has dried, develop the chromatograms in methyl ethyl ketone, till the front distance of 10 cm has reached. After removing the strips from the tank, let them dry in air and record the chromatogram by gamma scanner.
Expected R_f values:

Labelled complex	0.0 – 0.1
Free $^{99m}TcO_4^-$	0.9 – 1.0

Specification: Technecium-succimer complex: not less than 95%.
Impurity A ([^{99m}Tc]pertechnetate ion): ≤ 2%.

IZOTOP

PACKAGE LEAFLET: INFORMATION FOR THE USER
DMSA 1.5 mg powder for solution for injection
Dimercaptosuccinic acid (DMSA)

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.
- 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 DMSA is and what it is used for

This medicine is radiopharmaceutical for diagnostic use containing radioactive isotope.
^{99m}Tc-DMSA injection prepared from DMSA kit is a diagnostic radiopharmaceuticals contains ^{99m}Tc-technecium isotope radioactive sterile injection for intravenous administration. Use of DMSA is permitted only in departments of nuclear medicines.
^{99m}Tc-DMSA injection is a colourless solution, administered intravenously. After intravenous administration, ^{99m}Tc- DMSA is transported to the kidneys via the blood circulation, allowing to perform various diagnostic examinations of kidney by imaging technique.
As the medicine contains gamma-emitting 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. The pictures can give your doctor valuable information about the structure and working of the organ helping this way to choose the best treatment.
^{99m}Tc-DMSA is suitable for kidney scintigraphy, static imaging of kidney, determination of positions of the kidneys by means of imaging, determination of functional mass of kidney, determination of relative functions of right and left kidneys.
The use of ^{99m}Tc-DMSA injection does involve exposure to small amounts of radioactivity. Your nuclear medicine doctor has 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 DMSA is used

DMSA must not be used
- if you are allergic (hypersensitive) to the active substance or any of the other ingredients of DMSA (listed in section 6),
- if you are pregnant or breast feeding, 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 ^{99m}Tc-DMSA 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 of ^{99m}Tc-DMSA 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 adolescents
Talk to your nuclear medicine doctor, if you are under 18 years old.

Other medicines and ^{99m}Tc-DMSA
Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, since they may affect the interpretation of the images.

Using DMSA with food and drink
You can take DMSA with any food or drink.

Pregnancy and breast-feeding
You must inform the nuclear medicine doctor before the administration of ^{99m}Tc-DMSA if this is a possibility you might be pregnant, if you have missed your period or if you are breast-feeding. When in doubt, it is important to consult your nuclear medicine doctor who will supervise the procedure.
Pregnancy
Your nuclear medicine doctor will only administer this medicine during pregnancy if a benefit is expected which would outweigh the risks.
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. Nuclear medicine doctor tell you when you can resume breast-feeding.

Driving and using machines
It is considered unlikely that DMSA 1.5 mg powder for solution for injection will affect your ability to drive or to use machines.

3. How DMSA is used

There are strict laws on the use, handling and disposal of radiopharmaceutical products. ^{99m}Tc-DMSA 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.
^{99m}Tc-DMSA injection is prepared by mixing the content DMSA kit and radioactive ^{99m}Tc-pertechnate at the site of the use (hospitals, clinics). The injection is administered intravenously.
The nuclear medicine doctor supervising the procedure will decide on the quantity of ^{99m}Tc-DMSA injection to be used in your case. It will be the smallest quantity necessary to get the desired information.

Use in children and adolescents
In children and adolescents, if the doctor decides to perform the examination the quantity to be administered will be adapted to the child's weight.

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

After administration of ^{99m}Tc-DMSA injection
Drink large amounts of fluid and urinate frequently in order to eliminate the product from your body. This prevents the radioactive substance from accumulating in the bladder.
The nuclear medicine doctor will inform you if you need to take any special precautions after receiving ^{99m}Tc-DMSA. Contact your nuclear medicine doctor if you have any questions.

What should you do if you received overdose of the medicinal product?
There are strict rules and regulations on handling, use and disposal of radioactive materials. Since ^{99m}Tc-DMSA is given by a doctor under controlled conditions, the probability of overdose is low. However, in the case of an overdose, you will receive the appropriate treatment. In particular, the nuclear medicine doctor will advise you to drink lots of liquid which will accelerate the elimination of the drug from your body. You should take all necessary precautions against the contamination of your environment with radioactivity. Comply with the instructions given by your doctor.^{99m}Tc-DMSA which is temporarily present in your body and the excreted material loose their radioactivity in a natural way.
Should you have any further questions on the use of this medicine, please ask 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.
The use of ^{99m}Tc-DMSA injection does involve exposure to small amounts of radioactivity. Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. However these effects are hardly expected regarding the applied amount of activity.
Adverse event and reactions have not been reported ever since the authorization of the product (1989). Considering the number of the examinations carried out since, no adverse reactions are expected.
The amount of radioactivity in the body from ^{99m}Tc-DMSA is small. It will be passed out of the body in a few days without any intervention. If you have any further questions on the use of this medicine, ask your doctor.

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 DMSA 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.
Hospital staff will ensure that the product is stored correctly and not used after expiry date stated on the label.
The following information is intended for the specialist only.
Keep out of the reach and sight of children.
Keep out of the reach and sight of the people who are not authorized to handle, use or transport this product.
Kit (DMSA 1.5 mg powder for injection) should be store in refrigerator at 2°C - 8 °C. Keep the bottle in the outer carton in order to protect from light.
The radiolabelled injection (^{99m}Tc-DMSA injection) is to be stored below 25°C and protected from light. Storage of the radiolabelled injection should be in accordance with national regulation on radioactive materials.
^{99m}Tc-labelled DMSA must be used within 8 hours.
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 DMSA 1.5 mg powder for injection contains
- The active substance is 1.5 mg dimercaptosuccinic acid (DMSA) per vial.
- Other ingredients are: stannous(II)chloride dihydrate, ascorbic acid, calcium gluconate.
- The active substance of the labelled, radioactive DMSA: ^{99m}Tc-DMSA.

What DMSA looks like and contents of the pack
The DMSA injection vials contain: white, sterile, pyrogen-free powder (lyophilisate).
Sterile, 6 ml injection vial, with winered (halobutyl) rubber stopper, with green, flip-off plastic shield with rolled aluminium cap. Multidose vial.
One box contains six vials.

Marketing Authorisation Holder and Manufacturer
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