

PRODUCT
INFORMATION

Pentastan DTPA Reagent Multi Dose Vials

Description

Each vial contains 25 mg of DTPA (Pentetic Acid), 1250 micrograms (μg) of tin(II) chloride (equivalent to 1050 μg of anhydrous stannous chloride) and 4 mg of sodium chloride. The contents of the vial are lyophilised and stored under vacuum. The product is sterilised by gamma irradiation.

As supplied the product is sterile and pyrogen free.

The product contains no bactericide.

The product is designed for diagnostic use. Administration after reconstitution with sterile sodium pertechnetate $^{99\text{m}}\text{Tc}$ solution is by intravenous injection.

Physical Characteristics of $^{99\text{m}}\text{Tc}$

Technetium-99m, with a physical half-life of six hours, decays by isomeric transition to technetium-99. Photons associated with this transition which are useful for detection and imaging studies are listed in Table 1. A decay chart is listed in Table 2.

Table 1

Principal Radiation	Mean % per Disintegration	Mean Energy (keV)
Gamma-2	87.2	140.5

Table 2:
Physical Decay Chart of $^{99\text{m}}\text{Tc}$

Hours	Fraction Remaining	Hours	Fraction Remaining
0	1.000	5	0.562
1	0.891	6	0.501
2	0.794	7	0.447
3	0.708	8	0.398
4	0.631		

External Radiation

The specific gamma ray constant for $^{99\text{m}}\text{Tc}$ is 0.19mGy per MBq-h at 1cm. The first half value thickness of lead for $^{99\text{m}}\text{Tc}$ is 0.2mm. A range of values for the relative attenuation of the radiation emitted by $^{99\text{m}}\text{Tc}$ resulting from the interposition of various thicknesses of lead is shown in Table 3.

Table 3:

Shield Thickness mm Pb	Coefficient of Attenuation (approx.)
0.2	0.5
0.95	0.1
1.8	0.01
2.7	0.001
3.6	0.0001

Pentastan DTPA Reagent

Multi Dose Vials

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Actions

Following intravenous injection, ^{99m}Tc -DTPA is rapidly distributed throughout the extracellular fluid space, where it is promptly cleared from the body by glomerular filtration. There is minimal binding to the renal parenchyma.

^{99m}Tc -DTPA tends to accumulate in intercranial lesions with excessive neovascularity or an altered blood-brain barrier. The agent does not accumulate in the choroid plexus.

Since the agent is excreted by glomerular filtration, the images of the kidneys obtained during the first few minutes after injection show the vascular pool within the kidney. Subsequent images represent radioactivity in both the collecting system and the renal pelvis.

Indications

^{99m}Tc -Pentastan may be used to perform kidney-imaging, brain imaging, to assess renal perfusion and to estimate glomerular filtration rate.

Contraindications

None known.

Warnings

Use During Pregnancy:

Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the foetus.

This radiopharmaceutical should not be administered to pregnant or nursing women or persons under 18 years of age unless the benefits to be gained outweigh the potential hazards. Ideally, examination of a woman of childbearing capabilities should be performed only during the 10 days following the onset of menses.

Use During Lactation:

Technetium (^{99m}Tc) is excreted in human milk. If administered to a nursing mother, formula feeding must be substituted.

Precautions

General

Radiopharmaceuticals should only be used by physicians who are qualified and licensed to handle radioactives. Contents of the kit are intended only for use in the preparation of technetium (^{99m}Tc) labelled DTPA. They should not be administered directly to the patient. Solutions containing Sodium Pertechnetate with antioxidants should not be used. At time of administration the solution should be crystal clear.

Dose Handling

Radiation exposure to clinical personnel must be minimised. Care and appropriate safety measures should always be used. Pentastan multi-dose contains no bactericide. Aseptic procedures must be used at all times when handling the product.

Patient Care:

Care should be taken to minimise unwanted radiation exposure to patients, consistent with proper patient management

Adverse Reactions

No adverse reactions have been reported.

Pentastan DTPA Reagent Multi Dose Vials

Dosage and Administration

Each vial contains Pentetic Acid intended for 5 doses.

Technetium (^{99m}Tc) Pentastan is prepared for clinical use as follows:

- (1) Using aseptic technique, add the required amount of sterile sodium pertechnetate (^{99m}Tc) solution.
- (2) Mix by shaking gently for 10 seconds.
- (3) Administer by IV injection within seven hours.

Note: The vial is sealed under vacuum. A vent needle is therefore not required when adding the sodium pertechnetate (^{99m}Tc) solution. If no vacuum is found in the vial it should be discarded.

It is recommended that reconstituted Pentastan be stored below 8°C, under refrigeration, and used within 7 hours of reconstitution.

The suggested dose for a normal (70kg) adult is:

Brain Scan: 400-800 MBq

Renal Scan: 200 MBq

For children, the dose should be reduced to that appropriate to the patients weight.

The patient dose should be measured with a suitable radioactivity calibrator immediately before administration. Radiochemical purity should be checked prior to administration. Shielding should be used when preparing Technetium (^{99m}Tc) Pentastan.

Radiation Dosimetry

The estimated absorbed radiation dose per MBq to an average (70kg) patient from an intravenous injection of Technetium (^{99m}Tc) Pentastan is shown in Table 4.

Table 4:
Radiation Dose Estimates (mGy. MBq⁻¹)

	Bladder Voided Regularly	Bladder not Voided
Kidneys	0.001	0.001
Bladder Wall	0.055	0.142
Whole Body	0.002	0.004
Ovaries	0.006	0.016
Testes	0.005	0.012

The radiation dose was calculated according to "MIRD" methods. Ref "S", Absorbed Dose per Unit Cumulated Activity for Selected Radionuclides and Organs, **MIRD Pamphlet No.11**, 1975.

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Presentation

Pentastan Agent is supplied as a sterile, vacuum sealed, freeze-dried product, in 10 mL multi-dose vials. There are five vials to a pack.

Expiry

Expiry is 12 months from the date of manufacture. The expiry date is found on the pack.

Storage

Pentastan Agent should be stored between 2-8°C. (Refrigerate. Do not freeze).

Amended to include TGA recommendations 19th August 1992. Amended to include safety warning 10th August 1993. Approved by TGA 21st September 1993.

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