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# Summary of Product Characteristics

## 1. BRAND NAME
Technetril, $^{99m}$Tc

## 2. GENERIC NAME
Technetium (99mTc) sestamibi

## 3. PHARMACEUTICAL FORM
Powder for solution for injection

## 4. COMPOSITION
Each vial contains:

| | |
|---|---|
| Stannous dichloride | 0,05 mg |
| Copper tetramibi tetrafluoroborate | 0,80 mg |
| L- cysteine hydrochloride monohydrate | 1,2 mg |
| Mannitol | 10,0 mg |
| Sodium dihydrogen | 11,0 mg |

1 ml of reconstituted product contains:

| | |
|---|---|
| Technetium-99m | 37 – 1850 MBq |
| Stannous dichloride | 0,017 mg |
| Copper tetramibi tetrafluoroborate | 0,267 mg |
| L- cysteine hydrochloride monohydrate | 0,4 mg |
| Mannitol | 3,33 mg |
| Sodium dihydrogen | 3,67 mg |
| Sodium chloride | 9,0 mg |
| Water for injections | less 1,0 mL |

## 5. DESCRIPTION
White powder.
Reconstituted product is a colorless, clear liquid.

## 6. PHYSICO-CHEMICAL PROPERTIES
Technetril, $^{99m}$Tc is a diagnostic radiopharmaceutical and represents the complex of technetium–99m with 2-methoxyisobutyl-isonitrile.
Isotope $^{99m}$Tc has a 6.04 hours half emitting gamma ray energy of 140 keV (90 %).

## 7. PHARMACOTHERAPEUTIC GROUP
This medicinal product is for diagnostic use only.
**ATC code V09GA01**

## 8. PHARMACOLOGICAL PROPERTIES

***Pharmacokinetics***

Technetril $^{99m}$Tc while the intravenous injection quickly leaves the bloodstream, and after 3 - 5 minutes its content in the circulating blood is not more than 2% of the injected amount. Maximum accumulation of the radiopharmaceutical in the healthy myocardium is observed to 5 minutes after injection and on average is (2,68 ± 0,1)% of the injected dose. This level of the myocardial capture remains unchanged within 3 hours which determines the optimal timing of the planar or single photon emission tomography which are 1-2 hours after intravenous injection. Radiopharmaceutical content in the lungs is slightly, and its excretion is considerably ahead of Technetril $^{99m}$Tc clearance from the myocardium. 5 minutes after injection in the lung there is not more than (2,12 ± 0,8)% of the injected amount.

Technetril $^{99m}$Tc leaves the body primarily through the hepatobiliary tract and small intestine (about 40% in two days) and partly by the kidneys - 15%.

## 9. INDICATIONS

To estimate the myocardial perfusion in various pathological processes that lead to the disorder of the blood supply (coronary atherosclerosis, acute myocardial infarction, post-infarction and postmyocarditic cardiosclerosis, coronary heart disease), as well as to visualizate the malignant tumors of lungs and breast.

## 10. CONTRADICTIONS

Pregnancy.

**Use during lactation**

If necessary the nursing mothers should abstain from nurse during 24 hours after the injection of the radiopharmaceutical.

## 11. DOSING AND ADMINISTRATION

Radiopharmaceutical preparation:

- 3 ml of eluate of technetium-99m generator under aseptic conditions is injected using a syringe into the vial piercing the rubber stopper with the needle;
- Do not use an air needle;
- If required, the eluate 0,9 % may be diluted previously by isotonic sodium chloride solution to the required volume activity;
- The vial containing the radiopharmaceutical is placed in a lead container and heated in a water bath for 15 minutes after boiling water. The water level in the water bath should be above the level of the radiopharmaceutical solution in the vial;
- The radiopharmaceutical is ready for use after cooling of the vial up to room temperature.

Radiopharmaceutical is injected intravenously.

When examining patients to evaluation the myocardial perfusion at rest and under stress test with an interval of about 24 hours of the study Technetril, $^{99m}$Tc is injected at 259 - 370 MBq for each study on an empty stomach or at least 4 hours after ingestion. After intravenous injection the patient is recommended to have a light breakfast (eggs, milk, excluding tea, coffee).

When visualizing malignant tumors the radiopharmaceutical is injected in an amount of 570 - 740 MBq per study. After 20 minutes after injection a planar (three projections) or single photon emission computed tomography is performed.

When examining patients with suspected malignant tumors of the breast, they are placed lying

on the stomach, with the breast omitted down, the detector is in a lateral position. One vial of the finished product can be used for the study of 5 patients.

**Table**

**Estimated Absorbed Radiation Dose after administration of the radiopharmaceutical "Technetril, $^{99m}$Tc"**

| Organs and systems | Radiation dose (mGr/MBq) |
|---|---|
| Urinary bladder | 0,019 |
| Stomach | 0,008 |
| Small intestine | 0,043 |
| Upper part of the large intestine | 0,083 |
| Lower part of the large intestine | 0,046 |
| Kidneys | 0,028 |
| Liver | 0,008 |
| Lungs | 0,003 |
| Muscles | 0,005 |
| Spleen | 0,005 |
| Pancreas | 0,008 |
| Heart | 0,006 |
| Thyroid gland | 0,010 |
| Leather | 0,002 |
| Red marrow | 0,005 |
| Skeleton | 0,006 |
| Testes | 0,003 |
| Ovaries | 0,018 |
| Whole body (effective dose) mSv/MBq | 0,009 |

**Side effects**
Side effects when using the radiopharmaceutical for diagnostic purposes have not been identified. In rare cases, after the injection appears short metallic taste in the mouth.
Allergic reactions are possible.

**Overdosage**
After a single dose the overdose is unlikely due to the lack of pharmacodynamic properties of the radiopharmaceutical.

**Interactions**
While conducting diagnostic study the interaction with other radiopharmaceuticals has not been found.

**Warnings**
The work is performed according with national regulation on radioactive materials.

**Package**
Powder for solution for intravenous injection (vials).
5 vials in contoured cellular packaging and the instruction for medical use of the radiopharmaceutical are packaged in a cardboard box.

**Storage**

Powder should be stored at 2 – 10 ºC. The deviation of temperature (18-25$^{o}$C) for transportation within 1 month is allowable.
Storage of radiopharmaceuticals should be in accordance with national regulation on radioactive materials.

**Expiry**
Powder – 1 year after production date.
Technetril, $^{99m}$ Tc is used within 5 hours after preparation.