1. NAME OF THE MEDICINAL PRODUCT
NanoScan, kit for radiopharmaceutical preparation

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Active substance: Human serum albumin nano sized colloidal 500 micrograms.

3. PHARMACEUTICAL PARTICULARS

3.1. ROUTE OF ADMINISTRATION

- This medicinal product is for diagnostic use only.
- Inflammation scanning: 370-500 MBq as a single intravenous injection.
- Breast Cancer: Technetium-99m as single imaging activity by single or multiple injections.
- Malignant Melanoma: Total activity applied 40-100 MBq as a single intravenous injection.

3.2. METHOD OF ADMINISTRATION:

- The subcutaneous injection must be made without pressure into loose connective tissue.
- The injection volume should not exceed 0.2 - 0.3 ml. A maximum volume of 0.5 ml per injection site is critical.
- Sentinel node detection in:
  - Melanoma (stage IV)
  - Breast cancer

4. CLINICAL PARTICULARS

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

4.2. Administration

- Inflammation scanning:
  - The injection should be made intradermally or subcutaneously.

4.3. Contraindications

- Hyperчувствительность or anaphylactic reactions
- Pregnancy
- Breastfeeding

4.4. Interactions with other medicinal products and other forms of interaction

- Interaction studies have only been performed in adults.

4.5. Effects on ability to drive and use machines
NanoScan has no or negligible influence on the ability to drive and use machines.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties
At the chemical concentrations and activities used for diagnostic procedures **NanoScan** does not appear to have any pharmacodynamic effects.

5.2. Pharmacokinetic properties

- The **NanoScan** for lymphoscintigraphy is strictly contraindicated during pregnancy due to the possible accumulation in pelvic lymph nodes.

6. PHARMACOTHERAPEUTIC USES

6.1. List of excipients

- Sodium phosphate dibasic
- Sodium phosphate monobasic
- Stannous(II) Chloride dihydrate
- Sodium aluminium
- Stannic aluminium

6.2. Incompatibilities

- None known.

7. CLINICAL DATA

7.1. Population

- In very young children (up to 1 year) a minimum dose of 20 MBq (bone marrow scanning) is necessary in order to achieve diagnostic images.

7.2. Method of administration:

- This medicinal product should be reintroduced before administration to the patient. For the preparation of the radiopharmaceutical see section 5.1. This medicinal product should be reconstituted before administration to the patient. For the preparation of the radiopharmaceutical see section 5.1.

8. SAFETY DATA

8.1. Summary of product characteristics

- The following table presents how the frequencies are reflected in this section:

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/2000 to &lt;1/1000</td>
<td>Very common (≥1/100)</td>
</tr>
<tr>
<td>1/1000 to &lt;1/100</td>
<td>Common (≥1/1000)</td>
</tr>
<tr>
<td>1/1000 to &lt;1/100</td>
<td>Uncommon (≥1/10000)</td>
</tr>
<tr>
<td>&lt;1/10000</td>
<td>Rare (≥1/100000)</td>
</tr>
</tbody>
</table>

8.2. Preclinical testing

- Studies of genotoxicity, carcinogenicity and toxicity to reproduction have not been performed.

8.3. Clinical studies

- Inflammation scanning: Technetium-99m as single intravenous injection.

9. IMMUNE SYSTEM DISORDERS

- Protein allergy (hypersensitive) reaction

10. ADVERSE REACTIONS

- Exposure to ionising radiation is linked with cancer induction and a potential for development of secondary cancers. A single intravenous injection of 500 MBq when the maximum recommended activity of 500 MBq is administered these adverse events are expected to occur with a low possibility.

11. STORAGE

- Store in the original package in order to protect from light.
- Do not store above 25 °C.

12. WITHDRAWAL

- The product should be kept available during the study.

13. CONCLUDING REMARKS

- The radioactive product has ceased breastfeeding, and to what is the most appropriate choice of radiopharmaceuticals, above 0.5 mGy is regarded as a potential risk to the foetus.

14. PATIENT INFORMATION

- There is always a radiation-related risk. The radiation exposure should be the minimum consistent with achieving the desired clinical information.

15. LEGENDS

- a) Inflammation scanning: Technetium-99m Tc Tc-99m
- b) Breast Cancer: Technetium-99m Tc Tc-99m
- c) Malignant Melanoma: Technetium-99m Tc Tc-99m
- d) Potential for hypersensitivity or anaphylactic reactions
- e) Pregnancy
- f) Breastfeeding
- g) Hyperчувствительность or anaphylactic reactions
- h) Immune system disorders
- i) Protein allergy (hypersensitive) reaction

16. REFERENCES

- The available data on the production of **NanoScan** for lymphoscintigraphy is strictly contraindicated during pregnancy due to the possible accumulation in pelvic lymph nodes.

17. PATIENT INFORMATION

- This medicinal product may not be mixed with other medicinal products except those mentioned in section 6.6 a) and d).

18. SHELF LIFE

- Sheetal life after radiolabelling: 8 hours.
- Storage of radiopharmaceuticals should be in accordance with national regulation on radiopharmaceuticals.

19. SPECIAL PRECAUTIONS FOR STORAGE

- It is kept available during the study.

20. STABILITY

- In the original package in order to protect from light.
- Do not store above 25 °C.

21. NATURE AND CONTENTS OF CONTAINER

- Aluminium caps) with turned up edge.
Dose calculations were made with the standard MIRED method (MIRD Pamphlet No.1, Society of Nuclear Medicine, 1976) (For use with 99mTc NanoScan injection).

Biokinetic model

The typical procedure is to inject about 20 MBq 99mTc colloid immediately adjacent to the breast tumour, which is to be operated on. The patient is investigated with a gamma camera 4 hours after injection, the tumour and operated on for the first time to determine the distribution of 99mTc in the lymph nodes should be identified. In some situations the injected 99mTc is removed in its entirety by about 6 hours, but in normal conditions, after 12 hours it may be extended to 18 hours in some circumstances. The only significant radiation absorbed dose is that to surrounding tissues, mainly long as a result of maternal breast feeding during the few hours of exposure. This dose is considered to be generally very small.

Current ICPR dosimetric models do not permit calculation of dose from breast as a source organ, and because the doses are likely to be very small the TG does not consider it necessary to develop a new dosimetric model which breast is treated as a source organ.

Leakage of radionuclides from the injection site into the systemic circulation is not considered likely, anyhow, leakage such as backupto injected "colloid" model.

Organs

<table>
<thead>
<tr>
<th>Adult</th>
<th>Male</th>
<th>Female</th>
<th>Child</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adrenals</td>
<td>0.0011</td>
<td>0.0011</td>
<td>&lt;0.0002</td>
</tr>
<tr>
<td>Bladder wall</td>
<td>&lt;0.0005</td>
<td>&lt;0.0005</td>
<td>0.0001</td>
</tr>
<tr>
<td>Brain</td>
<td>0.001</td>
<td>0.001</td>
<td>&lt;0.0005</td>
</tr>
<tr>
<td>Kidneys</td>
<td>0.0088</td>
<td>0.0088</td>
<td>0.00015</td>
</tr>
<tr>
<td>Skeletal Muscle</td>
<td>0.0039</td>
<td>0.0039</td>
<td>&lt;0.0005</td>
</tr>
<tr>
<td>Lung</td>
<td>0.0003</td>
<td>0.0003</td>
<td>0.0003</td>
</tr>
<tr>
<td>Liver</td>
<td>0.0088</td>
<td>0.0088</td>
<td>0.00015</td>
</tr>
<tr>
<td>Large Intestine, upper colon</td>
<td>0.0037</td>
<td>0.0037</td>
<td>&lt;0.0005</td>
</tr>
<tr>
<td>Small Intestine, upper colon</td>
<td>0.0037</td>
<td>0.0037</td>
<td>&lt;0.0005</td>
</tr>
<tr>
<td>Small Intestine, lower colon</td>
<td>0.0037</td>
<td>0.0037</td>
<td>&lt;0.0005</td>
</tr>
<tr>
<td>Stomach</td>
<td>0.0025</td>
<td>0.0025</td>
<td>0.0005</td>
</tr>
<tr>
<td>Heart</td>
<td>0.0103</td>
<td>0.0103</td>
<td>0.002</td>
</tr>
<tr>
<td>Ovaries</td>
<td>0.0015</td>
<td>0.0015</td>
<td>&lt;0.0005</td>
</tr>
<tr>
<td>Muscles</td>
<td>0.0003</td>
<td>0.0003</td>
<td>0.0003</td>
</tr>
<tr>
<td>Pancreas</td>
<td>0.0062</td>
<td>0.0062</td>
<td>0.0012</td>
</tr>
<tr>
<td>Pelvis</td>
<td>0.0015</td>
<td>0.0015</td>
<td>0.0005</td>
</tr>
<tr>
<td>Pituitary</td>
<td>0.0005</td>
<td>0.0005</td>
<td>&lt;0.0005</td>
</tr>
<tr>
<td>Platelet</td>
<td>0.0004</td>
<td>0.0004</td>
<td>&lt;0.0005</td>
</tr>
<tr>
<td>Red bone marrow</td>
<td>0.00086</td>
<td>0.00086</td>
<td>0.00016</td>
</tr>
<tr>
<td>Spleen</td>
<td>0.0014</td>
<td>0.0014</td>
<td>0.00024</td>
</tr>
<tr>
<td>Skin</td>
<td>0.00006</td>
<td>0.00006</td>
<td>0.00012</td>
</tr>
<tr>
<td>Remaining organs</td>
<td>0.00006</td>
<td>0.00006</td>
<td>0.00012</td>
</tr>
</tbody>
</table>

Effective Dose per unit activity administrated (mSv/MBq)

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

When preparing the kit before administration is not radioactive, however, after Sodium Pertechnetate 99mTc Injection Ph.Eur. (activity: 185 MBq to 5.5 GBq) using shielded syringe.

2. Adjointdose

The combined occupational exposure to the vial and personnel handling the vial should not exceed 0.15 mSv to 5.5 Gy (550 rad).

3. Instructions for use

Complete the plate by adding the appropriate isotope and time setting. The radioactivity is determined using suitable detector. The retrieved result is used for determining the total activity.

4. Container closure

After reconstitution, the container and any unused contents should be disposed of in accordance with local requirements.

5. Instruction for Quality Control

Use aseptic procedure throughout and take precautions to minimize radiation exposure by the use of suitable shielding. Water-proof gloves should be worn during the preparation procedure.

6. Injections

The administration of radiopharmaceuticals creates risks for others from external radiation or contamination from spill of ionising radiopharmaceuticals in accordance with national regulations must therefore be taken. In children, it is possible to dilute the product up to 1.50 sodium chloride for injection. This product is not intended for internal use.

7. Dependencies

Intravenous administration is recommended. The biokinetic model is based on the assumption that administered activity only is that administered in the vial.

8. Test Conditions

The kit should be stored in a suitable location at ambient temperature. The radiation should be handled in a shielded area.

9. Administration

The administration of radiopharmaceuticals creates risks for others from external radiation or contamination from spill of ionising radiopharmaceuticals in accordance with national regulations must therefore be taken.

10. Use of measures

Intravenous administration is recommended. The radiopharmaceuticals should be prepared in a manner which satisfies both radiation safety and radiopharmaceutical quality requirements. Appropriate aseptic precautions should be taken.

11. Contraindications

Radiopharmaceuticals should be prepared in a manner which satisfies both radiation safety and radiopharmaceutical quality requirements. Appropriate aseptic precautions should be taken.

12. Special precautions for disposal and other handling

General warnings

The administration of radiopharmaceuticals creates risks for others from external radiation or contamination from spill of ionising radiopharmaceuticals in accordance with national regulations must therefore be taken.

13. Storage

Intravenous administration is recommended. The radiopharmaceuticals should be prepared in a manner which satisfies both radiation safety and radiopharmaceutical quality requirements. Appropriate aseptic precautions should be taken.

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