Sodium Pentetate (DTPA) for labeling with \(^{99m}\text{Tc}\)
Liofilizado para inyección iv.

**Pharmacological Category**

Diagnostic agent for the detection of renal disorders, intracranial lesions and disorders of the respiratory system.

**Composition.**

Each vial contains:

<table>
<thead>
<tr>
<th>Component</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium trisodium Pentetate</td>
<td>5.00 mg</td>
</tr>
<tr>
<td>Dihydric tin chloride</td>
<td>0.25 mg</td>
</tr>
<tr>
<td>Ascorbic acid</td>
<td>0.15 mg</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>5.00 mg</td>
</tr>
<tr>
<td>Injection water</td>
<td>c.s.p. 1 mL</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>c.s.</td>
</tr>
<tr>
<td>Hydrochloric acid</td>
<td>c.s.</td>
</tr>
</tbody>
</table>

**Pharmacology.**

Radiopharmaceuticals used in cerebral and renal gammagraphy, as is the case, have a common denominator: its prompt distribution throughout the fluid. Calcium Trisodium Calcium \(99m\text{Tc}\) is excreted through glomerular filtration in the kidney. As a result, it is possible to quantify glomerular filtration rate. The preparation \(99m\text{Tc}-\text{Calcium Trisodium Pentetate-Sn}\) is able to cross the damaged blood-brain barrier and accumulates in portions of the brain which cannot be accessed when the blood-brain barrier is intact.

**Pharmacokinetics.**

The following data were obtained from the literature consulted:

Plasma clearance is very rapid with a mean time of approximately 70 minutes; binding of 5-10% of the plasma proteins during the first hour [2]. According to reports, approximately 5% binds to plasma proteins. The fraction that binds to blood cells is insignificant (around 0.5% en 20 min). In 24 hours, around 4-5% of the dose is distributed extensively throughout the tissue; biliary expression is insignificant. Activity in the renal cortex reaches its highest peak in approximately 2 to 4 minutes after administration of the bolus: the average renal transit time is 3.0±0.5 min. In patients with normal kidney function, 95% of the dose is eliminated in 24 hours.

The pharmacokinetic parameters of the preparation \(99m\text{Tc}-\text{Trisodium Calcium Pentetate}\) are presented in the following table:

**Indications.**

Diagnostic radiopharmaceutical used for:

- Dynamic renal gammagraphy for examining the function of each kidney separately, diagnosis of renal - vascular hypertension, differential diagnosis between dilation and obstruction of the excretion system and evaluation of the function and perfusion of a implanted kidney
- Static and dynamic cerebral gammagraphy for the diagnosis and study of expansive cerebral lesions, strokes, arterial-venous malformations and cranial traumas.
- Gammagraphy of pulmonary ventilation and alveolar exchanges for the diagnosis and study of pulmonary thromboembolisms and other respiratory disorders.

**Contraindications.**

- Hypersensitivity to any of the components in the formulation.
- This preparation should not be administered to nursing mothers as sodium pertechnetate\(^{99}\) is passed on to the maternal milk during this period.
- This preparation should be handled only by qualified personnel duly authorized to handle radiopharmaceuticals.
- Administer to pregnant women only when strictly necessary as it is not known if this
radiopharmaceutical can cause fetal damage or affect fertility.

Precautions

- This preparation should be administered only by qualified personnel duly authorized to handle radiopharmaceuticals.
- Administer to pregnant women only when strictly necessary as it is not known if this radiopharmaceutical can cause fetal damage or affect fertility.

Warnings

- Make sure that both the patient and clinical staff working with radiopharmaceuticals receive as little radiation as possible.
- This preparation is sterile and non-pyrogenic and must therefore be handled aseptically.
- The content of the vial is supplied only for preparing $^{99m}$Tc-Pentetate Calcium Trisodium-Sn and therefore should not be administered without prior reconstitution with Sodium Pertechnetate $^{99m}$Tc.
- The reagents in the kit are not radioactive, however, after reconstituting with sodium pertechnetate [$^{99m}$Tc] the solutions must be stored with in a protective armored casing.
- Labeling reactions with $^{99m}$Tc must maintain tin ions in its reduced state and consequently sodium pertechnetate $^{99m}$Tc injections with oxidants should not be administered.
- El 99mTc-Pentetato calcium trisodium should not be used 5 hours after its preparation. Keep the preparation at room temperature.

Interaction with other Medications.

The administration of this preparation concomitantly with medications containing aluminum may yield false results when determining glomerular filtration rate.

Adverse Reactions.

Administration of radiopharmaceuticals to patients will inevitably generate a certain amount of radiation, however somatic or genetic damage have been reported only during long term treatments Although this risk may initially seem insignificant it must be borne in mind whenever treating a patient with radiopharmaceuticals. The use of these preparations is justified as long as the benefits outweigh the possible risks posed by the use of radioactive material. Allergic reactions due to the use of radiopharmaceuticals in most cases exhibit several clinical symptoms such as fever, flush, nausea and a variety of rashes such as urticaria and erythema. Other types of allergic reactions associated with the endovenous administration of the radiopharmaceuticals: pain or irritation at the administration site of the preparation.

Dose.

Diagnostic Dose: Intravenous injection in the event of:
- Renal gammography: 0.25 MBq (0.07mCi) per Kg of body weight administered intravenously
- Cerebral gammography: 8 MBq (0.21mCi) per Kg of body weight administered intravenously
- Pulmonary perfusion gammography: 11MBq (0.3mCi) per Kg of body weight in a maximum volume of 3mL in the nubilizer of a radioactive aerosol system.

Overdose.

There are no reports of symptoms due to an overdose of this product. Medical studies with radionuclides are conducted at very low concentrations and consequently produce no pharmacological effects. The only probable effect due to an overdose would be the additional radiation of the patient. The dose absorbed with an injection of Pentetate$^{99m}$Tc is low and safe and therefore does not require any special action when administering.

Instructions.

Use a hypodermic needle to extract 4 to 5 mL of Sodium Pertechnetate [$^{99m}$TcO$_4$] which may contain a maximum of 3700 MBq (100 mCi). The activity selected will depend on the patient’s body weight and the type of study to be carried out. Remove all the air in the needle as soon as possible. Shake the vial for one or two minutes until the lyophilized has been completely dissolved. The final solution is colorless and transparent.

Storage.

The product is stored at 2 y 8°C. After reconstitution the preparation is stored at room temperature in a lead casing.
Radiological safety measures

The same measures normally used when handling open source diagnostic preparations, in keeping with the regulations in force in the country.

Presentation:

Code: 2011   Kit containing 5 vials

Registration No.:

1429