Phytate-Sn for labeling with 99mTc (PHYTATE)

Pharmacological category
Diagnostic agent for liver gammagraphy

Composition

Each vial contains:

<table>
<thead>
<tr>
<th>Component</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Phytate</td>
<td>25.0 mg</td>
</tr>
<tr>
<td>Tin chloride Dihydrate</td>
<td>1.0 mg</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>5.0 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

It is known that Hexaphosphoric Acid of Inositol (Phytic Acid) is active in the absorption of calcium and phosphorous by the body and soluble in water in the form of sodium salt. However, it forms insoluble complexes with other metals such as Ca, Fe and Zn. In the blood, Phytic acid binds with calcium ions forming colloidal particles which are captured by the reticuloendothelial system, principally by Kupffer cells in the liver. The intravenous administration of 99mTc-Sn-Phytate is used for hepatic gammagraphy since it retains its capacity to react “in vivo” with calcium ions in the blood forming 99mTc-Sn-Ca-phytate, a colloid which is engulfed by the cells of the reticuloendothelial system, allowing the organ to be easily visualized although it is also possible to observe the spleen and bone marrow.

Pharmacokinetics.

Indications.

This preparation is used for gammagraphy of the liver for detecting traces of tumors, cirrhosis, hepatitis and other disorders.

Contraindications.

None have been reported in the international literature.

Precautions.

- This preparation should be handled only by qualified personnel duly authorized to handle radiopharmaceuticals.
- Administer to pregnant women only when absolutely necessary as it is not known if this radiopharmaceutical can cause fetal damage or affect fertility.
- This preparation should not be administered to nursing mothers as it has been reported that Sodium Pertechnetate is excreted into the maternal milk.

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 only for use with 99mTc-Calcium Trisodium Pentetate -Sn, and therefore should not be administered without prior reconstitution with Sodium Pertechnetate 99mTc.
- The reagents in the kit are not radioactive, however, after reconstituting with Sodium Pertechnetate [99mTc] the solutions must be stored in a protective armored casing.
- Labeling reactions with 99mTc must maintain tin ions in its reduced state and consequently Sodium Pertechnetate 99mTc injections with oxidants should not be administered.
- 99mTc -Phytate-Sn should not be used six hours after preparation.

Adverse Reactions

Administration of radiopharmaceuticals to patients will inevitably generate a certain amount of radiation, however somatic changes 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, nauseas 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.

Up to the present, international bibliographic references specifically in reference to this product have not been found since the sources consulted referred to its colloidal form. Nor was there any reference to experiments conducted in laboratory animals. The dose absorbed by humans when Tc-Phytate-Sn is injected is presented in the chart titled “Dose”.

Dose:

**Diagnostic dose:** The preparation is administered intravenously making sure that the patient receives 1.6 MBq (40 µCi) per kg of body weight. Images can be observed 30 - 60 min after administering the preparation.

**Instructions for use.**

Use a hypodermic needle to extract 4 to 5 ml of Sodium Pertechnetate $^{99m}$TcO$_4^-$ the lyophilized will be labeled with the desired activity according to the patient's body weight as indicated in the section titled “Dose” indicated below. Taking into consideration the volume contained in the vial, is possible to label even with 3.7 GBq (100 mCi)). Remove all the air in the needle. Shake the vial for one or two minutes until the lyophilized has been completely dissolved. The final solution is colorless and transparent.

Irradiation dose absorbed following an injection with $^{99m}$Tc-Phytate-Sn

<table>
<thead>
<tr>
<th>Organ</th>
<th>Dose absorbed mrad/µCi</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone marrow</td>
<td>0.027</td>
</tr>
<tr>
<td>Spleen</td>
<td>0.21</td>
</tr>
<tr>
<td>Liver</td>
<td>0.34</td>
</tr>
<tr>
<td>Ovaries</td>
<td>0.0056</td>
</tr>
<tr>
<td>Testicles</td>
<td>0.0011</td>
</tr>
</tbody>
</table>

The product must be stored at 2- 8°C. After reconstitution the product is stored at room temperature in an appropriate lead casing.

**Radiological Safety.**

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

**Presentation:**

- **Code:** 2014
- **kit with 5 vials**

**Registration No.:**

- **1044**

**Storage.**