<table>
<thead>
<tr>
<th><strong>for labelling with $^{99m}$Tc radionuclide</strong></th>
<th><strong>DTPA (diethylenetriamino pentaacetic acid) in vivo kit</strong></th>
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</thead>
<tbody>
<tr>
<td><strong>Product code:</strong></td>
<td>Tc-IK-8</td>
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<tr>
<td><strong>Marketing Authorization Number:</strong></td>
<td>OGYI-T-9244/01</td>
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</table>
| **Composition (per vial):** | Diethylenetriamino pentaacetic acid 9.0 mg
Stannous chloride dihydrate 0.6 mg
Ascorbic acid 0.5 mg
Sodium chloride 20.0 mg |
| **Indications:** | **Radioisotope diagnostics**
- Dynamic studies of kidney (function of kidney) by imaging technique
- Examination of the cerebral blood circulation
- Diagnosis of vascular and neoplastic brain injuries
- Examination of the gastrointestinal tract by using $^{99m}$Tc-DTPA labelled foodstuff or drink
- Examination of liquor circulation |
| **Administration:** | For studies of the renal function, the cerebral blood circulation and the gastrointestinal tract:
- intravenous injection
- For liquor circulation:
- lumbar or cisternal puncture |
| **pH:** | 5 – 8 |
| **Labelling efficiency:** | $> 90 \%$ |
| **Method of administration:** | Content of one vial – depending on the activity of the $^{99m}$Tc-pertechnetate used for labelling - can be divided to 3 - 6 portions. |
| **Posology:** | **Proposed activity to be administered to one patient in case of:**
Examination of renal function: 111–185 MBq
Examination of cerebral blood flow: 500–600 MBq
Examination of the gastrointestinal tract: 20–40 MBq
Examination of liquor circulation: 111-185 MBq |
| **Lumbar or cisternal puncture:** | Intravenous administration: the labelled solution can be directly administered.|
Lumbar or cisternal puncture: 3 ml of sodium pertechnetate should be introduced into the vial of DTPA kit and then it should be diluted with 3 ml of water for injection. This solution having a volume of 6 ml can be used for lumbar or cisternal administration. |
| **Contraindications:** | RELATIVE CONTRAINDICATIONS
- below 18 years of age
- pregnancy or lactation, except if the necessity and importance of obtaining the diagnostic information prevails the risk originating from the radiation exposure |
**ABSOLUTE CONTRAINDICATIONS**
if the patient does not provide an oral or written consent of being examined by using radionuclide |
| **Storage:** | Store DTPA in vivo kit in its own paper box, at room temperature. |
Store $^{99m}$Tc-DTPA injection at room temperature. Comply with the regulations for radiation safety. |
| **Expiry time:** | 1 year from manufacture. |
| **Packaging:** | Primary packaging material of the sterile, bacterial endotoxin-free, freeze-dried powder for solution for injection is glass vial closed with rubber stopper and aluminium cap. The labelled vials are supplied in a white carton box, which contains:
- 6 glass vials for 6 labelling procedures
- 1 Summary of Product Characteristics
- 6 empty, self-adhesive labels with radiation symbol |