CUSTODIOL® HTK solution

DESCRIPTION

Composition
1000 mL CUSTODIOL® HTK Solution contains:

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Amount</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium chloride</td>
<td>0.8766 g</td>
<td>15.0 mmol/L</td>
</tr>
<tr>
<td>Potassium chloride</td>
<td>0.6710 g</td>
<td>9.0 mmol/L</td>
</tr>
<tr>
<td>Potassium hydrogen 2-ketoglutarate</td>
<td>0.1842 g</td>
<td>1.0 mmol/L</td>
</tr>
<tr>
<td>Magnesium chloride • 6 H₂O</td>
<td>0.8132 g</td>
<td>4.0 mmol/L</td>
</tr>
<tr>
<td>Histidine hydrochloride • H₂O</td>
<td>3.7733 g</td>
<td>18.0 mmol/L</td>
</tr>
<tr>
<td>Histidine</td>
<td>27.9289 g</td>
<td>180.0 mmol/L</td>
</tr>
<tr>
<td>Tryptophan</td>
<td>0.4085 g</td>
<td>2.0 mmol/L</td>
</tr>
<tr>
<td>Mannitol</td>
<td>5.4651 g</td>
<td>30.0 mmol/L</td>
</tr>
<tr>
<td>Calcium chloride• 2 H₂O</td>
<td>0.0022 g</td>
<td>0.015 mmol/L</td>
</tr>
</tbody>
</table>

in sterile Water for injections
Anion: Cl⁻ 50 mEq

Physical Properties
pH 7.02 - 7.20 at 25°C
pH 7.4 - 7.45 at 4°C
Osmolality: 310 mosmL/kg
STERILE and pyrogen free. Sterilisation method - heat

INTENDED USE
CUSTODIOL® HTK Solution is indicated for the preservation of multiorgan transplants (kidneys, liver, pancreas, heart and lung) together with venous or arterial segments. The solution is left in the organ vasculature during hypothermic storage and transportation (not for continuous perfusion) to the recipient.

CUSTODIOL® HTK Solution is for single use only

WARNINGS AND PRECAUTIONS

Do not use the solution if it is not clear or if the container is damaged

Warning: Perfusion of the kidney, liver and/or heart should be carried out with a maximum hydrostatic pressure of 120 mm Hg.

Warning: CUSTODIOL® is not indicated for intravenous or intraarterial administration. It is indicated only for selective perfusion of the kidney, liver, pancreas, heart and lung for cooling of the surface areas, i.e., for the preservation of the donor organ during the transport from donor to recipient. CUSTODIOL® may not be used for systemic infusion.

Warning: CUSTODIOL® is not indicated for continuous perfusion.

Warning: Keep out of reach of children.

Caution: The product must be used before the expiration date stated on the package.

Caution: The product must be stored according to the recommendations prior to use – see “How Supplied”.
ADVERSE EFFECTS

No side effects have been encountered that could be attributed to this product.

INSTRUCTIONS FOR USE (Recommendations)

Required Equipment:

Perfusion apparatus with a Y-piece for bottle or bags, Perfusion cannula tube 2.5 to 3 mm, tube clamp, perfusion stand with a height setting of up to 200 cm with tape measure. Cooling Equipment (5 to 8°C) for use in cardiac surgery; perfusion tube with an internal diameter of 6 mm; transport container with sterile pouch for transport of the cooled organ from donor to recipient.

Filtration of CUSTODIOL® is not necessary or recommended.

Tolerance of Ischemia by the Kidney

The kidney may be stored with ice cold CUSTODIOL® solution at about 2 to 4°C with a period of (cold) ischemia of up to 48 hours. Warm ischemia time, that is to say the average time period required for the completion of anastomosis of the vessels, is usually 30 minutes. Taking this time as a basis, the organ recovers completely with optimal immediate function within 24 hours.

Tolerance of Ischemia by the Liver

The liver may be stored with ice cold CUSTODIOL® solution at about 2 to 4°C with a period of (cold) ischemia of up to 15 hours. Warm ischemia time, that is to say the average time period required for the completion of anastomosis of the vessels, is usually 30 minutes. Taking this time as a basis, the organ recovers completely with optimal immediate function within 24 hours.

Tolerance of Ischemia by the Pancreas

The pancreas may be stored with ice cold CUSTODIOL® solution at about 2 to 4°C with a period of (cold) ischemia of up to 15 hours. Warm ischemia time, that is to say the average time period required for the completion of anastomosis of the vessels, is usually 30 minutes.

Tolerance of Ischemia by the Heart

The Heart may be stored with ice cold CUSTODIOL® solution at about 2 to 4°C with a period of (cold) ischemia of up to 4 hours. Warm ischemia time, that is to say the average time period required for the completion of anastomosis of the vessels, is usually 30 minutes.

Lung, Vein and/ or Artery Transplantation

Lung preservation requires the addition of prostaglandins prior to perfusion of the lungs. The perfusion protocol for lungs is at the discretion of the individual transplant program.

The vein transplant (usually part of the great saphenous vein) or alternatively, the artery transplant (usually part of the internal thoracic artery) is cooled and stored in cold CUSTODIOL® solution (about 50 to 100 mL) at 5-8°C. After removal from the solution the segment of vein or artery is implanted.
**Introduction of Renal Perfusion**

Following successful laparotomy, the kidney is prepared by ligature of the capsular vessels. The perfusion catheter for selective kidney perfusion is fixed in the renal artery using a tourniquet. Cold perfusion (2-4°C) is performed under hydrostatic pressure (maximum of 120 mmHg). Within the first minute of perfusion, the renal vein is incised and clamped off adjacent to the vena cava. The escaping perfusate is removed from the abdominal cavity. After approximately 10 minutes of perfusion, the kidney is resected before transplantation.

**Transport of a Donor Organ**

The transport of a donor organ to the recipient utilizes a sterile pouch accommodating the size of the organ in an ice cold CUSTODIOL® solution. The organ must be completely covered by the solution. The pouch is sealed with adhesive tape and is placed into a second container which is also filled with CUSTODIOL® solution in order to prevent a breakdown of insulation and cooling by trapped air. The double-bagged organ is placed into a sterile plastic container and closed with a secure lid. The plastic bag is then placed into a transport container packed with ice for transport. Information about the donor, copies of the laboratory results and blood samples from the donor are also included. The transport of the donor organ in CUSTODIOL® solution must be accomplished as quickly as possible.

**How Supplied**

Bags of 1000 mL

Store at 2°C to 15°C and protect from light.

Registration **AUST R 205386**

**Distributed by:**

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