

# PRESERVATION SOLUTION

## v **StoreProtect Plus®**

**Container with perfusion and preservation solution  
for organs intended for transplantation**

### INSTRUCTIONS FOR USE

**EN**

p.d. 14 Tirpala transplantuojam organ konservavimui

 **carnamedica**

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 **2274**

**Container contents:****Solution for perfusion and cold storage of organs for transplantation StoreProtect Plus®**

p.d. 14 Tirpala transplantuojam organ konservavimui

**DESCRIPTION**

Composition: 1000 ml solution contains:

Lactobionic acid	35.8 g	105 mmol/l
Adenosine	1.336 g	5 mmol/l
Allopurinol	0.136 g	1 mmol/l
Glutathion	0.922 g	3 mmol/l
Polyethylene glycol (PEG 35)	1 g	1.0 g/l
Potassium dihydrogen phosphate	3.402 g	25 mmol/l
Raffinose, 5H <sub>2</sub> O	17.84 g	30 mmol/l
Magnesium sulphate, 7H <sub>2</sub> O	1.232 g	5 mmol/l
Sodium Hydroxide		qs pH: 7.4
Water for injection		qs 1000 ml

Sterilus, donorinius organus konservuojantis tirpalas, tinkantis kepenims bei kasos salei ms. Tirpalo sud. tis 1000ml: Lactobionic acid 35,8 g; Adenosine 1,336 g; Allopurinol 0,136 g; Glutathion 0,922 g; Polyethylene glycol (PEG 35) 1 g; Potassium dihydrogen phosphate 3,402 g; Raffinose, 5 H<sub>2</sub>O 17,84 g; Magnesium sulphate, 7 H<sub>2</sub>O 1,232 g; Sodium Hydroxide qs pH 7,4 ; Water for injection qs 1000 ml. Supakuotas permatomuose maišuose po 1000ml ir 2000ml. Medicinos priemonė III saugumo klasės. Pagamintas naudojant aseptinį užpildymą.

StoreProtect Plus® is a clear to light yellow, sterile, non-pyrogenic solution intended for the flushing and the hypothermic storage of organs (kidney, liver, pancreas). StoreProtect Plus® has an osmolality of approximately 290 mOsm/kg and sodium concentration of 120 mmol/l, potassium concentration of 25 mmol/l and pH of approximately 7.4 at room temperature.

**ACTIONS**

StoreProtect Plus® solution, cooled at +2°C and +6°C, is used for flushing of the isolated organ immediately before its removal from the donor and/or immediately after its removal from the donor. The solution is then left in the organ vasculature during hypothermic storage and transportation. StoreProtect Plus® is not intended to be used with continuous machine perfusion. Administration of StoreProtect Plus® at the recommended temperature will effectively cool the organ and lower its metabolic requirements.

**INTENDED USE**

V StoreProtect Plus® is intended for the flushing and the hypothermic storage of kidney, liver and pancreas organs at the time of organ removal from the donor, in preparation for storage, transportation and eventual transplantation into the recipient.

**CONTRAINDICATIONS**

There are no known contraindications when used as directed.

**WARNING**

NOT INTENDED FOR DIRECT INJECTION OR INTRAVENOUS INFUSION.

**PRECAUTIONS**

StoreProtect Plus® includes components (allopurinol) which, when administered individually, have caused hypersensitivity reaction in patients. Physicians should be stay alert to treat possible reactions.

**ADVERSE REACTIONS**

Vascular complications (thrombosis, fistulas, primary non-functions, graft rejections, dialysis needs, biliary complications after transplantation) have been reported in clinical trials of StoreProtect Plus®. However, those post-transplantation reactions could not be attributed solely to StoreProtect Plus®.

**PREPARATION**

Cool the solution to 2°C – 6°C. Remove overwrap prior to use. Check each bag for leaks by squeezing the container. If a leak is found, discard solution bag. With the overwrap removed, perform a visual inspection of the solution for visible particulate matter. Do not use the solution if obvious particulate matter, precipitates, or

contamination are evident in the solution. Use an administration set to flush the organ with StoreProtect Plus® solution. Prior to connection to the organ, the solution container should be suspended at a sufficient height to allow for a steady stream of solution and to produce flow rates of at least 30 ml/min during flushing. Flushing should be continued until the organ is uniformly pale and the effluent is clear.

### Suggested minimum volumes:

In situ aortic flush:	Ex vivo infusion:	
Adults 2000 ml – 4000 ml Infants 50 ml/kg	<ul style="list-style-type: none"> <li>• Liver Adults 1200 ml Infants 50 ml/kg</li> </ul>	<ul style="list-style-type: none"> <li>• Kidney / Pancreas Adults 300-500 ml Infants 150-250 ml</li> </ul>

Additional solution should be dispensed into the container holding the organ. The organ must be totally immersed. Seal the container aseptically. The organ storage container should be maintained within a well-insulated transport container. Ice should be used to surround the organ storage container, but should not be used within the container, where the ice could come into direct contact with the organ. Prior to transplantation the donor organs must be flushed to remove StoreProtect Plus® according to transplantation centers protocols. Those operations must be done by qualified operators.

### PACKAGING AND STORAGE

Bag material EVA (PVC free). 1000 ml StoreProtect Plus® Solution in 10 one-liter (1000 ml) or 5 two-liter (2000 ml) bas per one carton box. Store StoreProtect Plus® may be stored at a temperature between +2°C and +25°C keep away from direct sunlight. Avoid excessive heat. Do not freeze the solution, and do not use if frozen.

Supakuotas permatomuoše maišuose po 1000ml ir 2000ml.

### ATTENTION

This medical device is to be used only by the qualified medical staff.

 Date of production	 Caution! See instruction for use.	 2274	The product meets the requirements of the European Medical Devices Directive MDD. The manufacturer is certified by the Notifying Authority No. 2274
 Expiration date	 Do not use if damaged.		The product includes instruction for use.
 Series number	 Sterile (Aseptic filling) <i>Pagamintas naudojant aseptinį užpildymą.</i>	 +2°C	Restriction of acceptable storage temperatures
 Catalog number	 Single use		Non-pyrogenic
 Keep away from sunlight.	 Medical Device	 Manufacturer	Carnamedica Sp. z o.o. ul. Olszynki Grochowskiej 21 lok. U6 04-281 Warsaw, Poland