



**GLOBAL
TRANSPLANT
SOLUTIONS**

U.S.A.
1875 E. Main St., Suite 12
Duncan, SC 29334
1-888-487-4404
CustomerService@GlobalTransplantSolutions.com
www.GlobalTransplantSolutions.com

CANADA
1 St. Clair Ave West, Suite 403
Toronto, ON M4V 1K6

PRODUCT INFORMATION LEAFLET

SERVATOR B SALF

SOLUTION FOR FLUSHING AND COLD STORAGE OF KIDNEY, LIVER, AND PANCREAS ORGANS

NOT FOR DIRECT INJECTION OR INTRAVENOUS INFUSION

COMPOSITION: 1000 ml solution contains:

Pentafraction	50 g/L	N.A
Lactobionic Acid (as Lactone)	35.83 g/L	(105 mmol/L)
Potassium Phosphate monobasic	3.4 g/L	(100 mmol/L)
Magnesium Sulfate heptahydrate	1.23 g/L	(27 mmol/L)
Raffinose pentahydrate	17.83 g/L	(5 mmol/L)
Adenosine	1.34 g/L	(1 mmol/L)
Allopurinol	0.136 g/L	(25 mmol/L)
Total Glutathione	0.922 g/L	(5 mmol/L)
Potassium Hydroxide	5.61 g/L	(30 mmol/L)
Sodium Hydroxide/Hydrochloric Acid	Adjust to pH 7.4	
Water for Injection	q.s.	

SERVATOR B SALF is a clear to light yellow, sterile, non-pyrogenic solution for hypothermic flushing and storage of organs. The solution has an approximate calculated osmolarity of 320 mOsm, a sodium concentration of 29 mEq/L, a potassium concentration of 125 mEq/L, and a pH of approximately 7.4 at 20°C.

ACTIONS

SERVATOR B SALF must be cooled to 2° to 6°C (36° to 43°F) ® prior to use. The cold solution is used to flush the isolated organ immediately before removal from the donor and/or immediately after removal from the donor. The solution is then left in the organ vasculature during hypothermic storage and transportation. SERVATOR B SALF is to be used for cold storage of the organ and is not acceptable for continuous machine perfusion. Administration of SERVATOR B SALF, at the recommended temperature, will effectively cool the organ and lower its metabolic requirements.

INTENDED USE

SERVATOR B SALF is intended for the flushing and cold storage of donated kidney, liver and pancreas organs at the time of organ removal from the donor in preparation for storage, transportation and eventual transplantation into a recipient.

CONTRAINDICATIONS

Hypersensitivity to adenosine, allopurinol, or any component of SERVATOR B SALF solution or suggested additives.

WARNINGS

NOT INTENDED FOR DIRECT INJECTION OR INTRAVENOUS INFUSION

PRECAUTIONS

The donor organ must be flushed free of the SERVATOR B SALF prior to the reperfusion. The organ must be flushed with physiological solution to prevent occurrence (in the recipient) of potentially serious cardiovascular complications such as hyperkalemic cardiac arrest or bradyarrhythmia. This is necessary because of the high concentration of potassium in the solution. These precautions must be taken during donor organ retrieval to avoid cardiac arrest.

SERVATOR B SALF includes components (allopurinol and pentafraction) which individually have caused

hypersensitivity reaction in patients. Additionally, the additives recommended for use with SERVATOR B SALF (penicillin, insulin, and dexamethasone) have individually been associated with hypersensitivity reactions in patients. Physicians should consult individual drug labeling and be alert to treat possible reactions.

ADVERSE REACTIONS

Cardiovascular complications such as bradyarrhythmia have been reported in cases where the organ has been refushed with fresh solution within a short period (1 to 3 hours) prior to release of vascular anastomosis clamps in the recipient, or when inadequate flush-out of the solution has occurred.

A few anecdotal reports when this solution was used in liver graft preservation described clinical problems including hepatic functional changes, poor outcomes including death, and biopsies showing ischemic damage in the liver with or without signs of mild rejection.

PREPARATION AND ADMINISTRATION WITH LIVER, KIDNEY AND PANCREAS

Cool the solution to 2° to 6°C (36° to 43°F). Remove overwrap prior to use. Check each bag for leaks by squeezing the container firmly. If a leak is found, discard solution container. With the overwrap removed, perform a visual inspection of the solution for particulate matter. Do not use the solution if obvious particulate matter, precipitates, or contamination are evident in the solution.

The following can be added aseptically to each liter of SERVATOR B SALF immediately before use:

- Penicillin G, 200,000 units per liter
- Regular Insulin, 40 units per liter
- Dexamethasone, 16 mg per liter

The use of these additives is not required but rather is at the discretion of the Organ Procurement or Transplant professional.

Glutathione, one of the components of SERVATOR B SALF, oxidizes during storage. If desired, an additional 0.922 g/L (3 mmole/L) of glutathione may be added if Transplant Center policy or Surgical Personnel requirements call for its use. (Boudjema et al, *Transpl. Proc.* 23[5]1991; Merion et al, *Transpl. Proc.* 23[4]1991).

Remove protective cap from the bag outlet port, designated as delivery set port. Insert the spike from the administration set into the bag port with a twisting motion. Open clamp on administration set. Hold the administration set vertically above the solution bag, then squeeze solution bag to fill administration set. Close the clamp.

Prior to connection to the organ, the solution container should be suspended from a sufficient height to allow for a steady stream of solution and to produce flow rates of at least 30 mL/min during flushing. Open the clamp to begin flushing. Flushing should be continued until the organ is uniformly pale and the effluent is relatively clear.

SUGGESTED MINIMUM VOLUMES

In situ aortic flush:	Adults, 2 – 4 L Infants, 50 mL/kg
Ex vivo infusion:	liver (via portal vein and biliary tree) Adults, 1200 mL Infants, 50 mL/kg
Pancreas or Kidney:	Adults, 300 – 500 mL Infants, 150 – 250 mL

Additional solution should be dispensed into the container holding the organ. 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.

Donor organs must be flushed free of SERVATOR B SALF prior to anastomosis (Refer to PRECAUTIONS Section.). In order to minimize residues of the solution in the liver, just prior to anastomosis, flush one liter of Lactated Ringer's solution through the hepatic portal vein.

ISCHEMIA TIMES

The recommended following times for each organ are:

Cold Ischemia Times

Liver not longer than 17 hours
Kidney not longer than 23 hours
Pancreas not longer than 21 hours

Warm Ischemia Times

Liver not longer than 2.5 hours
Kidney not longer than 2.5 hours
Pancreas not longer than 2.5 hours

HOW SUPPLIED: 1000 mL bags, shelf carton of 10 bags
2000mL bags, shelf carton of 5 bags

Store SERVATOR B SALF indoors at temperatures controlled between 2° and 25°C (36° and 77°F) until use. Avoid excessive heat.













Do not freeze the solution, and do not use if frozen. Do not use if discolored or if obvious particulate matter, precipitates, or contamination are evident in the solution.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

MANUFACTURER: S.A.L.F. S.p.A. LABORATORIO FARMACOLOGICO
via Marconi, 2 - 24069 Cenate Sotto (BG) Italy

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SYMBOLS USED ON THE PRIMARY PACKAGING AND BOX LABELS			
	Do not reuse – for single use		Manufacturer
	Product code		Sterilized using steam or dry heat
	Lot Number		Temperature limit for warehouse storage
	Expiry date		Protect from light and heat
	Do not use if the package is opened or damaged		Do not resterilize
	Consult instructions for use		Non – pyrogenic
RxOnly	CAUTION: Federal law restrict sale of this device to or on the other of a physician or licensed practitioner.		