



Instructions for Use



SilverStream® is a hypertonic buffered solution, with hydrogel properties and a pleasant odor, for wound management and maintenance of wound moisture level. SilverStream® is a clear, colorless solution, protected from microbial contamination by a low concentration of ionic silver and supplied in 100ml, 250ml and 500ml bottles.

INTENDED USE AND INDICATIONS FOR USE

SilverStream® is intended for use under the supervision of a healthcare professional for mechanical cleansing and removal of foreign material including micro-organisms and debris from wounds such as stage I-IV pressure ulcers, stasis ulcers, diabetic foot ulcers, post-surgical wounds, first and second-degree burns, cuts abrasions and minor skin irritations.

GENERAL DIRECTIONS FOR USE

SilverStream® is designed for management and moisturizing of wounds by applying the SilverStream® solution directly from the bottle, by means of a syringe or bulb, spraying onto the wound using a spray bottle, by applying with devices designed to allow for irrigation or lavage, or by soaking a gauze/dressing or sponge. Apply 1-2 times daily, according to the physician instruction. Between dressing with SilverStream® changes, wash the wound with water or soap and water. Before removal of the gauze/dressing or sponge, moisten with SilverStream® solution for easier removal.

Note: The wound may be cleansed if SilverStream® is applied with a 19G needle (application pressure of ~ 10 psi).



CAUTIONS AND WARNINGS

- For external use only. Avoid contact with eyes.
- Use only undamaged bottle.
- Do not use in patients with a history of hypersensitivity to any of the ingredients.
- Discontinue use if irritation develops.
- Avoid usage of turbid or colored solution.
- Protect bottle from direct contact with wound. Bottles that have come into contact with the wound must be discarded after use.
- For single patient use only.
- If the bottle is closed immediately after use and the top of the bottle is protected from contamination, the solution may be reused within 28 days from first opening.
- Store below 30°C / 86°F in a dry place.
- The empty bottle can be disposed to the regular trash can. A bottle that contains solution should be cleared off to an appropriate site.
- Do not apply more than 700ml of SilverStream solution within 24 hours.

INGREDIENTS













Ingredients include water for injection (WFI), glycerol (glycerin), sorbitan monolaurate (Tween-20), TRIS, menthol and silver nitrate 0.01% (w/v).

Each ml contains an antimicrobial ionic silver in the form of silver nitrate 0.01% (w/v).

Each package contains twelve (12) bottles of 250ml or twenty-four (24) bottles 100ml or twelve (12) bottles of 500ml and instructions for use leaflet, which is part of the bottle label.

SYMBOLS

The following provides a description of the graphic symbols that appear on the SilverStream® label:

	Caution
	Consult instructions for use
	Manufacturer
	Keep bottles out of direct sunlight
	Temperature Limitation
	Use by date
	Sterilized using aseptic processing techniques
	Do not resterilize. Resterilization may reduce the effectiveness of the product
	Batch code / LOT #
	Keep out of reach of children
	19G needle (application pressure of ~ 10 psi)
	Medical Device