

SilverStream

Solution

Instructions for Use



US-FDA No.: K039227

R_x ONLY

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, ranging from colorless to pale yellowish 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 management and moisturizing of 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. Facilitate wound healing by applying the SilverStream® solution directly from the bottle on the wound in one of the 4 ways:

- (1) Applying by means of a syringe or bulb.
 - (2) Applying with device designed to allow for irrigation or lavage.
 - (3) Spraying onto the wound using a spray or foam bottle.
 - (4) Pouring onto a gauze/dressing or sponge.
1. Allow the wound to be exposed to the solution for 5-10 minutes. Do not rinse.
 2. If necessary, use SilverStream-soaked gauze to gently clean the wound using a circular motion, starting from the center and moving outward.
 3. Moisten sterile cotton gauze with SilverStream® solution and place the wet gauze on the wound according to the Medical Practitioner's instruction.
 4. Apply a secondary non-antimicrobial occlusive dressing as directed by the Medical Practitioner.

Apply 1-2 times daily, according to Medical Practitioner's instruction.

The SilverStream® solution may remain on the wound until the next dressing change.

It is recommended that the wound bed should be kept moist continuously with SilverStream®.

Maintaining a moist wound environment has been shown to promote wound healing.

Between dressing changes, it is recommended to moisten the gauze, dressing, or sponge with SilverStream solution before removal for easier dressing removal.

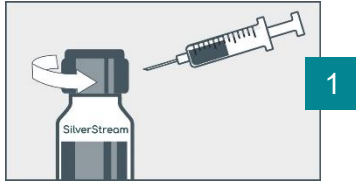
Between dressing changes, you may wash the wound with water or soap and water.

DO NOT INJECT.

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

DO NOT wash the wound with Saline, Before or After using SilverStream® as it may reduce the solution's efficacy.

DIRECTIONS FOR USE



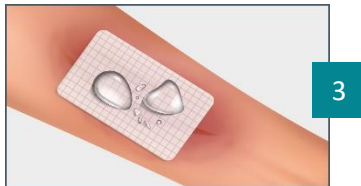
Step 1:

Open the cap, insert syringe with needle into the bottle and draw up the quantity of SilverStream® solution as advised by the Medical Practitioner.



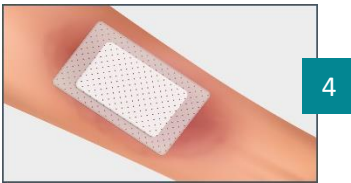
Step 2:

Spray the SilverStream solution on the wound. Let the wound be exposed to the sprayed solution for 5-10 minutes. Do not rinse. If needed, use SilverStream-soaked gauze to gently clean the wound. **DO NOT INJECT** (The needle should not touch the wound).



Step 3:

Wet a sterile cotton gauze with SilverStream® solution. Place the wet gauze on the wound.



Step 4:

Dress the wound with a dry secondary non-antimicrobial occlusive dressing, such as a pad with an adhesive edge or a bandage, as directed by the Medical Practitioner.

Between dressing changes, it is recommended to moisten the gauze, dressing, or sponge with SilverStream solution before removal for easier dressing removal.



CAUTIONS AND WARNINGS

- For external use only. Avoid contact with eyes.
- Use only undamaged bottle.
- Do not use in patients with history of hypersensitivity to any of the ingredients.
- Discontinue use if irritation develops.
- Avoid usage of turbid or intensely colored solution.
- Protect bottle from direct contact with the wound.
- Bottle that comes in direct 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 between 10°C-30°C (50°F-86°F) in a dry place.
- The empty bottle can be disposed to the regular trash can. A bottle that contains a solution should be cleared off to an appropriate site.
- Do not apply more than 700 mL of SilverStream® solution within a 24 hour period.

INGREDIENTS

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

Each mL contains 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:



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	Caution
 <small>eIFU indicator</small>	Consult instructions for use
	Keep bottles out of direct sunlight
	Temperature Limitation
	Single patient - multiple use
	Sterilized using aseptic processing techniques
	Do not resterilize. Resterilization may reduce the effectiveness of the product
	Do not use if package is damaged
	Keep out of reach of children
 <small>-10PSI 19-22G NEEDLE</small>	19G needle (application pressure of ~ 10 psi)
	Medical device
	Batch code / LOT #
	Date of manufacture Country of manufacture
	Use by date
	Catalog number
	Manufacturer
	Distributor
	UDI - Unique device identifier
	Prescription Device