

SilverStream[®] OTC

Ionic SilverStream[®] Solution

Instructions for Use Over the Counter Use (OTC)



US-FDA No.: K039227

SilverStream® OTC is a hypertonic buffered solution, with hydrogel properties and a pleasant odor, for skin wounds and burns management and maintenance of moisture level. SilverStream OTC 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 OTC is intended for the management and moisturizing of:

- Minor cuts
- Minor burns
- Abrasions
- Irritated areas

GENERAL DIRECTIONS FOR USE

SilverStream OTC is specifically formulated to manage minor cuts, minor burns, abrasions, and irritated areas on both the face and body, while also maintaining optimal moisture levels in the affected area.

It is ideal for wound treatment and may serve as an integral part of a first-aid kit.

To facilitate healing, apply the SilverStream OTC according to the following instructions:

1. Gently clean the affected area.
2. Apply SilverStream® OTC directly on the skin or on the wound and leave to dry as much as possible. Use a syringe or bulb or pour gauze to apply the solution. No need to rinse.
3. It can also be applied to the skin on gauze pad and then bandaged with a secondary dressing, such as a pad with an adhesive edge or a bandage.

Apply 1-2 times daily until complete wound healing or desired results are achieved.

Between dressing changes, it is recommended to moisten the gauze or dressing with SilverStream OTC solution to facilitate easier dressing removal.

DO NOT INJECT.

DO NOT wash the wound with Saline, Before or After using SilverStream OTC as it may reduce the solution's efficacy. Use water or soap and water to wash between dressing changes.



CAUTIONS AND WARNINGS

- For external use only.
- Avoid contact with eyes.
- Use only undamaged bottle.
- Do not use if you have a history of hypersensitivity to any of the ingredients.
- Discontinue use if irritation develops.
- Avoid usage of turbid or intense colored solution.
- For deep wounds or major burns, consult a healthcare professional.
- If pregnant or breastfeeding, consult a doctor or a pharmacist before use.
- Keep bottle away from the wound. Discard bottle if it touches the wound.
- Reclose bottle after use, reuse within 28 days.
- Store between 50°F-86°F (10°C-30°C) in a dry place.
- Disposal: Empty bottle: regular trash. Solution-filled: proper disposal.
- Do not apply more than 700 mL of SilverStream OTC solution within a 24-hour period.

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 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 products labels:



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	Caution
	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
	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