

vashegel[®]

Vashe[®] Antimicrobial Wound Gel

For Rx (Professional) and Over-the-Counter Use

Product Description:

Vashe Antimicrobial Wound Gel is an aqueous hydrogel that aids in the removal of foreign objects such as dirt, debris, and microorganisms from granulating wounds, and forms a protective barrier that provides for a moist wound environment which loosens contaminated exudate, slough, and other foreign materials within the wound bed. A moist wound environment is also supportive of the healing process by aiding autolytic debridement. The hypochlorous acid in Vashe Antimicrobial Wound Gel acts as a preservative to kill and inhibit growth of microorganisms in the bottle and on gauze or cover dressings.

Caution:

United States Federal Law restricts this device to sale by or on the order of a licensed healthcare practitioner in the state that this product is prescribed (when used for the Rx Indication listed below).

Indications for Use:

Rx (Professional Use) – Under the supervision of a healthcare professional, Vashe Antimicrobial Wound Gel is intended for management of wounds, including itch and pain relief, and to cleanse and moisten the wound bed. A moist wound and skin environment is beneficial to the healing process. It is intended for use on mechanically or surgically debrided wounds, Stage I-IV Pressure Ulcers, Partial- and Full-thickness Wounds, Diabetic Foot and Leg Ulcers, Post-Surgical Wounds, First- and Second-degree Burns, Grafted and Donor Sites, exit sites and intact skin, and various dermatoses, including contact dermatitis. It can be used during wound dressing changes to soften encrusted wound dressings.

OTC (For minor burns, skin irritations, lacerations, abrasions) – Vashe Antimicrobial Wound Gel is intended for use to relieve itch and pain from minor skin irritations, lacerations, abrasions, and minor burns; to cleanse and moisten the wound bed; and for the management of minor cuts, exit sites, and intact skin. It is also indicated for the management of irritation and pain from minor sunburn, and it can be used during wound dressing changes to soften encrusted wound dressings.

Role of the Preservative:

Hypochlorous acid acts as a preservative to kill and inhibit growth of microorganisms in the bottle and on gauze or cover dressings.

Directions for use:

Rx – Shake well before each use. Apply a generous layer to the affected and immediately surrounding areas. Use as directed by a healthcare professional. Use a cover dressing as necessary. Do not use after expiration.

OTC – Shake well before each use. Clean the area with cleanser or soap and water (or as directed by a healthcare professional) and blot dry. Apply a layer of gel to the affected and immediately surrounding areas. Apply once or twice daily or as directed by a healthcare professional. Use a cover dressing as necessary. Do not use after expiration.

Warnings:

Rx – Vashe Antimicrobial Wound Gel should not be used to treat any condition other than prescribed. Do not use if the seal is broken or missing. Do not transfer to another container. Contact a healthcare professional if signs of infection occur, there is a change in wound color and/or odor, the wound does not begin to heal, and/or any other unexpected symptoms occur. Avoid direct contact of the container with the wound. KEEP OUT OF REACH OF CHILDREN. For external use only. No known contraindications.

OTC – Vashe Antimicrobial Wound Gel should not be used to treat any condition other than as indicated for use as described above. Do not use if the seal is broken or missing. Do not transfer to another container. If condition worsens or persists for more than 7 days, contact a healthcare professional. Contact a healthcare professional if signs of infection occur, there is a change in wound color and/or odor, the wound does not begin to heal, and/or any other unexpected symptoms occur. Avoid direct contact of the container with the wound. KEEP OUT OF REACH OF CHILDREN. For external use only. No known contraindications.

Ingredients:

Sodium Magnesium Fluorosilicate, Water, and Hypochlorous Acid (0.050%) as a preservative to inhibit growth of microorganisms within the product and on gauze or cover dressings. This is a non-sterile product which contains preservatives.

Handling: Store with cap closed tightly after each use in its original container. Store between 5°C (41°F) and 25°C (77°F). Keep away from direct sunlight and heat sources. Do not freeze.

How Supplied: This product is supplied non-sterile.

Disposal: No special disposal considerations are required. Dispose of the tube and gel after the expiration dates.

Manufactured by:

Urgo Medical North America, LLC

Fort Worth, TX 76102

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