



NeutroPhase® Skin and Wound Cleanser (Rx Only)

INDICATIONS FOR USE:

NeutroPhase® Skin and Wound Cleanser is intended for use under the supervision of healthcare professionals for cleansing and removal of foreign material, including: microorganisms and debris from wounds; cleaning minor cuts, minor burns, superficial abrasions, and minor irritations of the skin; as well as moistening absorbent wound dressings. It is also intended for moistening and debriding acute and chronic dermal lesions, such as: Stage I-IV pressure ulcers, stasis ulcers, leg ulcers, diabetic foot ulcers, post surgical wounds, first and second degree burns, as well as grafted and donor sites.

DIRECTIONS FOR USE:

Apply NeutroPhase to irrigate, clean, and debride wounds and periwound tissue. No rinsing is necessary.

To moisten and lubricate a dressing, apply NeutroPhase to wound dressing and gently apply to wound bed. Moisten dressing with NeutroPhase as needed. When changing wound dressing, avoid excessive wetness.

USE PROCEDURES:

Instructions For Use Of Spray Pump:

1. Remove original cap from bottle of NeutroPhase.
2. Insert pump sprayer into NeutroPhase bottle and screw sprayer down securely.
3. Hold upright to spray NeutroPhase onto wound area.
4. Hold no closer than 3 inches to wound to avoid splashing while spraying.
5. Hold within 10 inches of the wound to avoid overspray of NeutroPhase.
6. Apply NeutroPhase as needed.

WOUND CLEANSING AND MOISTENING WOUND DRESSINGS:

1. Remove old dressing(s) from the wound as needed.
2. Irrigate the wound and periwound area with NeutroPhase to remove cellular debris and excessive wound drainage from the area to be treated. Wound may be moistened and cleansed with NeutroPhase as needed.
3. If the use of NeutroPhase is the primary means of wound cleansing, and when heavy amounts of necrotic tissue are present, more time may be required.

INCISIONAL CARE:

1. Spray NeutroPhase into the subcutaneous tissue prior to final closure of the dermis.
2. After completion of skin closure, NeutroPhase may be sprayed on the incision prior to applying a bandage.

DEBRIDEMENT:

1. When using a scalpel, forceps, scissors, curette, or other appropriate tool for excisional and/or sharp debridement, use NeutroPhase to rinse the wound during and after the procedure.
2. If the application of a pre-soaked dressing is not possible due to wound type or location, pour NeutroPhase directly onto the wound to flush or flood the wound for the required contact time.

CONTACT TIME:

Apply NeutroPhase as frequently as needed/as directed by your doctor.

HANDLING:

Non-toxic, non-sensitizing, and non-irritating to the skin and eyes. Harmless to common work surfaces. No special handling precautions required.

SHELF LIFE:

For an unopened bottle, refer to the expiration date on the bottle label. Upon opening, use contents within 60 days.

INGREDIENTS:

Neutrox® (pure hypochlorous acid, 0.03% as a preservative) in saline.

PRESERVATIVE EFFECTIVENESS:

NeutroPhase meets the anti-microbial preservative acceptance criteria (USP) for *P. aeruginosa*, *E. coli*, *S. aureus*, *C. albicans*, and *A. brasiliensis*.

IN-SOLUTION EFFECTIVENESS OF NEUTROPHASE:

NeutroPhase demonstrates rapid, in-solution, inactivation of selected Gram-positive species, Gram-negative species, and fungi (refer to the following table). Reductions in microbial viability in-solution have not been correlated with performance on the surface of skin in clinical trials.

IN-SOLUTION EFFECTIVENESS OF NEUTROPHASE AT 60 SECONDS:

MICROBIAL SPECIES	ATCC NUMBER	% REDUCTION	LOG REDUCTION
Gram-positive			
<i>Staphylococcus aureus</i> Methicillin-susceptible (MSSA)*	29213	>99.999	>5
<i>Staphylococcus aureus</i> Methicillin-resistant (MRSA)*	33591	>99.999	>5
<i>Staphylococcus epidermidis</i>	12228	>99.999	>5
<i>Staphylococcus haemolyticus</i>	29970	>99.99	>4
<i>Staphylococcus hominis</i>	27844	>99.99	>4
<i>Staphylococcus saprophyticus</i>	35552	>99.99	>4
<i>Streptococcus pyogenes</i> *	49399	>99.99	>4
<i>Corynebacterium amycolatum</i>	49368	>99.99	>4
<i>Enterococcus faecium</i>	51559	>99.99	>4
<i>Bacillus oleronius</i>	700005	>99.999	>5
<i>Clostridium perfringens</i> *	13124	>99.99	>4
<i>Propionibacterium acnes</i>	29399	>99.999	>5
Gram-negative			
<i>Acinetobacter baumannii</i>	19606	>99.99	>4
<i>Escherichia coli</i>	8739	>99.99	>4
<i>Enterobacter aerogenes</i>	51697	>99.999	>5
<i>Haemophilus influenzae</i>	49144	>99.999	>5
<i>Klebsiella pneumoniae</i> *	10031	>99.999	>5
<i>Moraxella catarrhalis</i>	8176	>99.9	>3
<i>Proteus mirabilis</i> *	14153	>99.999	>5
<i>Pseudomonas aeruginosa</i>	27853	>99.9999	>6
<i>Serratia marcescens</i>	14756	>99.999	>5
<i>Vibrio vulnificus</i> *	27562	>99.999	>5
<i>Bacteroides fragilis</i> *	25285	>99.999	>5
Fungi			
<i>Candida albicans</i>	10231	>99.99	>4
<i>Aspergillus brasiliensis</i>	16404	>99.99	>4

* These microorganisms are implicated in various chronic (e.g., pressure and diabetic ulcers) and acute (e.g., necrotizing fasciitis) infections.

STORAGE:

No special storage conditions are necessary. Store NeutroPhase in its original container. Non-flammable. Caution – do not freeze – glass bottle may break if frozen.

DISPOSAL:

Non-toxic and safe to the environment. No special disposal considerations required. Container may be recycled.

WARNING:

For external use only. Do not use for infusion or injection. Do not swallow. Use only undamaged bottles. In case of sensitivities to chlorine, please exercise caution and consult with your doctor prior to use. Do not use expired product. Do not use if solution is yellow, brown or not clear. To prevent contamination of the solution, take care that the open bottle does not make contact with the wound.

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