

PROLAVACID®

**Sunmedic**
Healing wounds. changing lives

Antimicrobial, rinsing,
cleansing gel and solution



Description:

In developing Prolavacid®, the goal has been to provide a antimicrobial product which meets the requirements and protocols of current best practice in wound management. Prolavacid®, a polyhexamethylene biguanide-based wound cleanser, is medically approved ingredients in a patented combination achieving the desired result of antimicrobial treatment, breakdown of antibiotic-resistant biofilms, and promotion of wound healing without tissue damage or irritation. As a result, Prolavacid® has been shown to be effective against both MRSA and biofilm bacterial and fungal strains *in vitro*. These strains include *Staphylococcus aureus* and *Pseudomonas aeruginosa*, commonly associated with chronic wounds and a shift to an infected state and increased virulence in wounds. These species also combine in biofilm with *Candida albicans*, a fungi contributing to delayed healing in chronic wounds. Combined in a biofilm, these strains are not effectively treated by currently available wound management products. Importantly, Prolavacid® has also been shown to have no significant negative effect on healing in preclinical study. Prolavacid® is designed for the purpose of cleansing, rinsing, moisturizing, and preventing the formation of biofilm on both acute and chronic wounds, as well as skin.

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Prolavacid® may be a promising treatment option for addressing the shortcomings of current wound care products and achieving enhanced cleansing outcomes in the management of acute and chronic wounds complicated by infection and biofilm.

Indications:

Prolavacid® is specifically indicated with the ultimate aim of minimizing the risk of wound infection for the following wounds type:

- | | |
|------------------------------------------|---------------------------------------------|
| 1- Diabetic foot ulcers | 8- Dehisced wounds |
| 2- Post-surgical wounds | 9- Granulating/epithelializing wounds |
| 3- First- and second-degree burns | 10- High volume exudating wounds |
| 4- Hard-to-heal acute and chronic wounds | 11- Sloughy wounds |
| 5- Venous leg ulcers | 12- Radiation and chemically induced wounds |
| 6- Traumatic wounds | 13- Dry skin conditions |
| 7- Cavity and deep wounds | 14- Stage I-IV pressure ulcers |

Warnings/Contraindications:

Prolavacid® is intended solely for external application on the skin, wounds, or designated application sites. Prolavacid® should not be used for the following cases:

- 1- If it is known or suspected that the patient may be allergic against any of the substances in the product.
- 2- On the CNS or meninges, in the middle or inner ear, in the eyes, on hyaline cartilage and on peritoneal cavity.

How to use:

- 1- The initial step in wound care involves the wound bed preparation principal.
- 2- The wound is first flushed with Prolavacid® wound cleansing solution to remove any dirt or loose deposits.
- 3- Subsequently, a sterile compress soaked in Prolavacid® wound cleansing solution is applied to the wound, where it is left in place to cover the wound for a period of 10-15 minutes, thereby enhancing the efficiency of the cleansing process.
- 4- To cover the wound surface adequately, and secured with a suitable dressing based on the wound's specific characteristics.

Composition:

Purified water, EDTA, Betaine, PHMB 0.1%, Glycerol.

Specifications:

Prolavacid® utilizes a cutting-edge formula that offers robust protection against a wide range of harmful microorganisms. Prolavacid® is made by patented best composition of EDTA and PHMB. Prolavacid® is designed to work quickly. The synergic effect between PHMB (Polyhexamethylene Biguanide), EDTA (Ethylene Diamine Tetraacetic Acid), Betaine, and glycerol refers to the enhanced efficacy or performance achieved when these substances are used together compared to when they are used individually. Within seconds, this powerful formula begins killing harmful microorganisms, leaving no room for compromise when it comes to your patients' health and safety.

Storage:

Proper storage of Prolavacid[®] is crucial to maintain its efficacy. It is advised to store the solution at room temperature, approximately between 4-25°C (39-77°F). Following the opening of the bottle, it is recommended to discard any remaining solution after one month to uphold the integrity and potency of the product. Shelf life is 24 months.

How to use Prolavacid[®] Irrigation solution 1000 ml with instillation and dwell time:

Healthcare providers can effectively use Prolavacid[®] Irrigation solution in combination with NPWTi-d to optimize wound healing, reduce the risk of infection, and improve patient outcomes. Before starting the NPWTi-d treatment, the wound should be thoroughly cleaned and debrided as necessary. Ensure that the wound bed is free of any necrotic tissue, debris, or biofilm, as these can hinder the effectiveness of the treatment. For a detailed and thorough explanation on the proper utilization of Prolavacid in conjunction with an iNPWT device, please consult the manufacturer's Instructions For Use (IFU). However, it is essential to closely monitor the wound and adjust the treatment plan as necessary to achieve the best results.

How to use Prolavacid[®] cleansing, rinsing solution 50, & 250 ml:

- 1- The initial step in wound care involves the wound bed preparation principal.
- 2- The wound is first flushed with Prolavacid[®] wound cleansing, rinsing solution to remove any dirt or loose deposits.
- 3- Subsequently, a sterile compress soaked in Prolavacid[®] wound cleansing solution is applied to the wound, where it is left in place to cover the wound for a period of 10-15 minutes, thereby enhancing the efficiency of the cleansing process.
- 4- If you have access to the Prolavacid[®] Debripad, you can use this to maximize cleaning as its surface with microfiber has an ability to capture and dissolve microparticles that can interfere with wound healing. Open the package, soak the pad with 20-30 ml of Prolavacid[®] wound cleansing, rinse solution. Debride with Debripad[®] the wound by gentle movements around the wound surface. Debripad[®] must be discarded after use.

How to use Prolavacid[®] Gel:

Following the cleansing as abovementioned description, the Prolavacid[®] Gel could be applied evenly 2-4 mm thick, to cover the wound surface adequately, and secured with a suitable dressing based on the wound's specific characteristics.

Appearance and smell:

Clear color and odorless

What is Biofilm and how it develops?

Biofilm is a complex, structured community of microorganisms that is attached to a surface and embedded in a self-produced slimy matrix, consisting of polysaccharides, proteins, and DNA. It forms when free-floating microorganisms attach themselves to a surface and begin to grow and reproduce. Biofilms can develop on various surfaces such as medical devices, pipes, teeth, or natural environments like rocks and water bodies. The development of biofilm occurs in several stages:

1. Attachment:

Microorganisms initially attach to the surface using flagella, pili, or adhesion molecules present on their cell surfaces. At this stage, the attachment is reversible and weak.

2. Colonization:

Attached microorganisms start to multiply and produce extracellular polymeric substances (EPS), which create the protective matrix that holds the biofilm together.







3. Growth and maturation:

As the biofilm expands, more microorganisms join the community and continue to produce EPS, gradually building up the structure and increasing microbial diversity.

4. Detachment and dispersion:

Some microorganisms detach from the biofilm and disperse into the surrounding environment, allowing them to colonize new surfaces and continue the biofilm development cycle.

Prolavacid® products list:

Description	Article No	Size	Image
Irrigation solution	PDI800510	1000 ml	
Cleansing solution	PDI800520	250 ml	
Cleansing solution	PDI800530	50 ml	
Cleansing spray	PDI800540	250 ml	
Cleansing gel	PDI800550	150 g	
Debripad	PDI800560	10 x 12 cm	

Thank you for choosing Sunmedic products for your wound healing needs.