

# **PROXIVOL- dressing, wound and burn, hydrogel w/drug and/or biologic Misemer Pharmaceutical**

-----  
**Proxivol**

Proxivol is a soothing wound gel that promotes a moist wound environment that is ideal for the healing process.

## **Directions:**

Cleanse wound then apply Proxivol to the wound and skin surrounding the wound 3 - 4 times daily.

## **Indications:**

For the local management of painful skin wounds, including:

- Pressure ulcers
- Venous stasis ulcers
- Superficial wounds and scrapes
- 1st and 2nd degree burns

## **Warnings:**

External use only. Do not use this product if you are allergic to any of the ingredients. Avoid contact with eyes. Sterile unless opened or damaged.

## **Caution:**

Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

## **Storage:**

Store at 25°C (77°F): excursions permitted to 15°-30°C (59°-86°F). Protect from freezing [See USP Controlled Room Temperature].

## **Ingredients:**

Water, Lidocaine HCl, Collagen, Aloe Vera gel, Sodium alginate, Glycerin, Hydroxyethylcellulose, Triethanolamine, Benzethonium chloride.

## **CALL YOUR DOCTOR ABOUT SIDE EFFECTS:**

**Call your doctor about side effects. You may report side effects to Misemer Pharmaceutical at 1-662-993-9625 or the FDA at 1-800-FDA-1088.**

## How Supplied:

Proxivol wound gel is supplied as a gel in:  
1 oz. (28.33g) tube, NDC 0276-0603-28

Distributed By:  
Misemer Pharmaceutical  
Ripley, MS 38663

Item 0603

Rev 1021

**MISEMER PHARMACEUTICAL**  
0276-0603-28  
Lidocaine 2% Gel  
Dispense by Prescription

**MISEMER PHARMACEUTICAL**  
0276-0603-28  
Dispense by Prescription

**Proxivol**  
Lidocaine 2% Gel

**Proxivol**  
Lidocaine 2% Gel  
Dispense by Prescription

**Dispense by Prescription**

**Dispense by Prescription**

**NET WT. 1 oz. (28.33 g)**

**NET WT. 1 oz. (28.33 g)**

A soothing wound gel that promotes a moist wound environment that is ideal for the healing process.

**DIRECTIONS** Cleanse wound then apply Proxivol to the wound and skin surrounding the wound 3 - 4 times daily.

**INDICATIONS** For the local management of painful skin wounds, including:  
• Pressure ulcers • Venous stasis ulcers • Superficial wounds and scrapes • 1<sup>st</sup> and 2<sup>nd</sup> degree burns

**WARNINGS** External use only. Do not use this product if you are allergic to any of the ingredients. Avoid contact with eyes. Sterile unless opened or damaged.

**CAUTION** Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

**STORAGE** Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F). Protect from freezing [See USP Controlled Room Temperature].

**INGREDIENTS:** Water, Lidocaine HCl, Procollagen, Sodium alginate, Glycerin, Hydroxyethylcellulose, Triethanolamine, Benzethonium chloride, Aloe barbadensis leaf extract.

**MISEMER PHARMACEUTICAL**  
0276-0603-28  
Dispense by Prescription

**MISEMER PHARMACEUTICAL**  
0276-0603-28  
Dispense by Prescription

**Proxivol**  
Lidocaine 2% Gel  
Dispense by Prescription

**Proxivol**  
Lidocaine 2% Gel  
Dispense by Prescription

**NET WT. 1 oz. (28.33 g)**

**NET WT. 1 oz. (28.33 g)**

Manufactured for:  
**MISEMER PHARMACEUTICAL**  
Misemer Pharmaceutical, Inc. Ripley, MS 38663  
Dispense in Original Container

Item 0603  
Rev 12220-1

3 02760 60328 7

## PROXIVOL

dressing, wound and burn, hydrogel w/drug and/or biologic

## Product Information

<b>Product Type</b>	PRESCRIPTION MEDICAL DEVICE	<b>Item Code (Source)</b>	NHRIC:0276-0603
---------------------	-----------------------------	---------------------------	-----------------

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>LIDOCAINE HYDROCHLORIDE</b> (UNII: V13007Z41A)	
<b>BOVINE TYPE I COLLAGEN</b> (UNII: FHJ3ATL51C)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>SODIUM ALGINATE</b> (UNII: C269C4G2ZQ)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%)</b> (UNII: R33S7TK2EP)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>BENZETHONIUM CHLORIDE</b> (UNII: PH41D05744)	

## Product Characteristics

<b>(SPLSTERILEUSE)</b>	false
<b>(SPLMRISAFE)</b>	true

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:0276-0603-28	28.33 g in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
premarket notification	K020540	02/01/2022	

**Labeler** - Misemer Pharmaceutical (784121365)

Revised: 2/2022

Misemer Pharmaceutical