

DERMAL WOUND CLEANSER- benzethonium chloride spray
Smith & Nephew Medical Ltd.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Dermal Wound Cleanser

DRUG FACTS

ACTIVE INGREDIENTS

Benzethonium Chloride 0.13%

PURPOSE

First aid antiseptic

USES

- first aid to help reduce the risk of infection in minor cuts, scrapes and burns
- aids in the removal of foreign materials such as dirt and debris

WARNINGS

- **For external use only**
- **Do not use in the eyes** or apply over large areas of the body
- **In case of deep or puncture wounds, animal bites, or serious burns, contact a doctor**
- **Stop use and contact a doctor** if the condition persists or gets worse. Do not use longer than 1 week unless directed by a doctor
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately

DIRECTIONS

- clean the affected area
- apply a small amount of this product on the area 1 to 3 times daily
- rinse as per normal protocol
- cover wound with sterile dressing or bandage as needed
- if applying dressing or bandage, let dry first

OTHER INFORMATION

- contains antimicrobial ingredient

INACTIVE INGREDIENTS

benzyl alcohol, citric acid, disodium EDTA, glycerin, polyquaternium-10, polysorbate 20, sodium citrate, water

QUESTION OR COMMENTS?

1 800 876-1261

**PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - DERMAL WOUND CLEANSER
BOTTLE, SPRAY (473 mL)**

Smith&Nephew

REF 449000

NDC 69740-490-00

**Dermal
Wound
Cleanser**

First Aid Antiseptic

- Helps reduce risk of infection in wounds and burns
- Gentle wound cleansing
- Safe and easy to use
- pH-buffered
- Non-irritating

16 fl. oz. (473 mL)

Made in the USA for Smith & Nephew Medical Ltd.

101 Hessle Road

Hull

HU3 2BN

England

www.smith-nephew.com

REF 449000



DERMAL WOUND CLEANSER

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Drug Facts

Active ingredient Benzethonium chloride 0.13% **Purpose** First aid antiseptic

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Questions or comments? 1 800 876-1261

Made in USA for
Smith & Nephew Medical Ltd,
101 Hessle Rd, Hull
HU3 2BN England.
www.smith-nephew.com



RM2710
24663

LOT 1234567890

EXP YYYY-MM

0369740490008

Room #

Name

PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - DERMAL WOUND CLEANSER BOTTLE, SPRAY (236 mL)

Smith&Nephew

#59449200

NDC 69740-492-00

Dermal Wound Cleanser

First Aid Antiseptic


- Helps reduce risk of infection in wounds and burns
- Gentle wound cleansing
- Safe and easy to use
- pH-buffered
- Non-irritating

8 fl. oz. (236 mL)

Made in the USA for Smith & Nephew Medical Ltd.
101 Hessle Road

Hull
HU3 2BN
England
www.smith-nephew.com

REF 59449200



DERMAL WOUND CLEANSER

First Aid Antiseptic

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NDC 69740-492-00

EAN
0369740492002

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LOT 1234567890

EXP YYYY-MM

Made in USA for
Smith & Nephew
Medical Ltd,
101 Hessle Rd, Hull
HU3 2BN England.
www.smith-nephew.com
RM3288
24662



Room #

Name

| DERMAL WOUND CLEANSER | | | |
|---|----------------|-----------------------|-----------------|
| benzethonium chloride spray | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69740-490 |
| Route of Administration | TOPICAL | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP) | | BENZETHONIUM CHLORIDE | 1.3 g in 981 mL |

| Inactive Ingredients | | | | |
|--|------------------|--|----------------------|--------------------|
| Ingredient Name | | | Strength | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | | | | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | | | | |
| WATER (UNII: 059QF0KO0R) | | | | |
| SODIUM CITRATE (UNII: 1Q73Q2JULR) | | | | |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | | | | |
| | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:69740-490-00 | 473 mL in 1.0 BOTTLE, SPRAY; Type 0: Not a Combination Product | 04/01/1994 | |
| | | | | |
| Marketing Information | | | | |
| Marketing Category | | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | | part333A | 04/01/1994 | |
| | | | | |

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| SODIUM CITRATE (UNII: 1Q73Q2JULR) | | | |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | | | |
| | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:69740-492-00 | 236 mL in 1.0 BOTTLE, SPRAY; Type 0: Not a Combination Product | 04/01/1991 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 04/01/1991 | |

Labeler - Smith & Nephew Medical Ltd. (216344051)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|---|
| Swiss-American CDMO, LLC | | 080170933 | MANUFACTURE(69740-490, 69740-492) , analysis(69740-490, 69740-492) , pack(69740-490, 69740-492) |

Revised: 10/2020

Smith & Nephew Medical Ltd.