

WOUND CLEANSER- wound cleanser spray
Dynarex Corporation

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.

3005 DynaWound Wound Cleanser Spray NDC 67777-403-01

Active Ingredient

Benzethonium Chloride 0.13%

Purpose

First Aid Antibiotic

Use(s)

First aid to help prevent infection in minor cuts, scrapes, and burns

Warnings

For External Use Only

Do not use

- In the eyes or over large areas of the body
- Longer than 1 week unless directed by a doctor

Ask a doctor before use if you have

deep or puncture wounds, animal bites, or serious burns.

Stop use and ask a doctor if

if condition persists or gets worse.

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- Clean the affected area
- Spray a small amount of this product on the area 1 to 3 times daily

- May be covered with a sterile bandage
- If bandaged let dry first

Other Information

- Store at room temperature 15°-30°C (59°-86°F)
- Avoid excessive heat

Inactive ingredients

Benzyl Alcohol, Disodium Edetate, Glycerin, Polyquaternium 10, Polysorbate 20, Purified Water, Sodium Citrate.

Label

Reorder No. 3005

Room #

DynaWound™ is a mild wound cleanser that is gentle on sensitive wounds.

- Excellent for removing exudates and debris
- pH balanced
- Non-toxic
- Convenient supplement to saline irrigation
- Easy to use trigger pump

LOT

Manufactured for:
Dynarex Corporation
10 Glenshaw Street
Orangeburg, NY 10962
USA • www.dynarex.com
Made in India

Patient Name

DynaWound™

Wound Cleanser

Drug Facts

| Active Ingredient | Purpose |
|---|----------------------|
| Benzethonium Chloride 0.13%... | First Aid Antiseptic |
| Use | |
| First aid to help prevent infection in minor cuts, scrapes and burns | |
| Warnings | |
| For external use only. | |
| Do not use | |
| <ul style="list-style-type: none"> ■ in the eyes or over large areas of the body ■ longer than 1 week unless directed by a doctor | |
| Ask a doctor before use if you have deep or puncture wounds, animal bites, or serious burns. | |
| Stop use and ask a doctor if condition persists or gets worse. | |
| Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. | |
| Directions | |
| <ul style="list-style-type: none"> ■ Clean the affected area ■ Spray a small amount of this product on the area 1 to 3 times daily ■ May be covered with a sterile bandage ■ If bandaged, let dry first | |
| Other information | |
| <ul style="list-style-type: none"> ■ Store at room temperature ■ Avoid excessive heat | |
| Inactive Ingredients | |
| Benzyl Alcohol, Disodium Edetate, Glycerin, Polyquaternium 10, Polysorbate 20, Purified Water, Sodium Citrate | |

NDC# 67777-403-01 R221216

SYMBOL GLOSSARY
For an explanation of symbols used in Dynarex packaging, visit [dynarex.com/symbols.php](http://www.dynarex.com/symbols.php)

8 fl. oz. (236.5 ml)

6 16784 30051 1

WOUND CLEANSER

wound cleanser spray

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:67777-403 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|---------------------|
| BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP) | BENZETHONIUM CHLORIDE | 0.13 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-----------------|
| BENZYL ALCOHOL (UNII: LKG8494WBH) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| POLYQUATERNIUM-10 (125 MPAS AT 2%) (UNII: L45WU8S981) | |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | |
| SODIUM CITRATE (UNII: 1Q73Q2JULR) | |
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|--|-----------------------------|---------------------------|
| 1 | NDC:67777-403-02 | 24 in 1 CASE | 02/13/2017 | |
| 1 | NDC:67777-403-01 | 236.5 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph not final | part333A | 02/13/2017 | |

Labeler - Dynarex Corporation (008124539)

Registrant - Dynarex Corporation (008124539)