

THERA PLUS PAIN RELIEF CLEANSING- benzalkonium chloride, lidocaine hydrochloride liquid
Fourstar Group USA, Inc.

Thera Plus Pain Relief Cleansing Spray

Drug Facts

Active ingredients

Benzalkonium chloride 0.13%

Lidocaine HCL 4%

Purpose

First aid antiseptic

Topical analgesic

Uses

for first aid to help prevent bacterial contamination or skin infection and for temporary relief of pain and itching associated with

- minor cuts
- scrapes
- minor burns
- sunburn
- minor skin irritations

Warnings

For external use only.

When using this product

- do not use in or near the eyes
- do not apply over large areas of the body or in large quantities
- do not apply over raw surfaces or blistered areas
- do not use longer than 1 week unless directed by a doctor

Ask a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burns

Stop use and ask a doctor if

condition worsens, or symptoms persists for more than 7 days or clear up and then

occur again within a few days.

Keep out of reach of children.

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

Directions

Adults and children 2 years of age and older:

- clean the affected area
- spray a small amount of this product to affected area 1 to 3 times daily
- may be covered with a sterile bandage, if bandaged, let dry first
- children under 2 years of age: do not use, ask a doctor before use

Other information

- store at room temperature 59° - 77° F (15°- 25° C).

Inactive ingredients

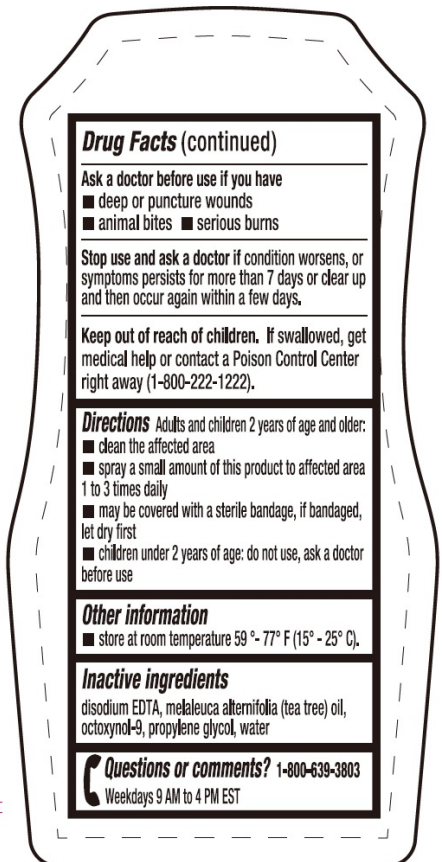
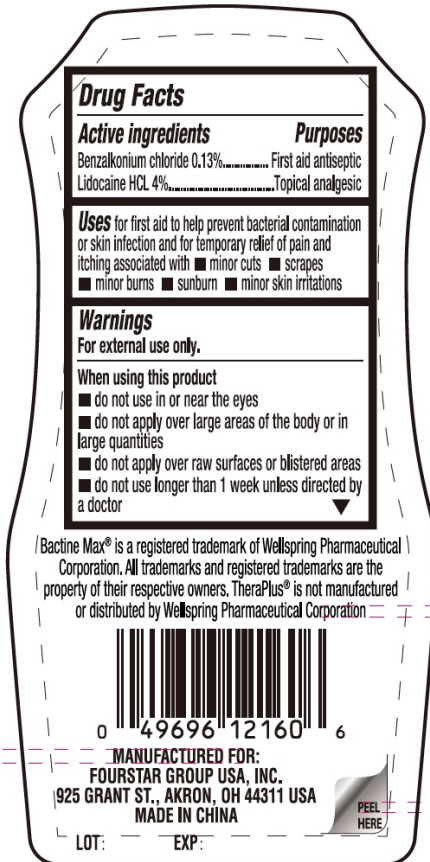
disodium EDTA, melaleuca alternifolia (tea tree) oil, octoxynol-9, propylene glycol, water

Questions or comments?

1-800-639-3803

Weekdays 9 AM to 4 PM EST

Package Labeling:



THERA PLUS PAIN RELIEF CLEANSING

benzalkonium chloride, lidocaine hydrochloride liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:80684-150 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------|----------------|
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | 1.3 mg in 1 mL |
| LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII: 98PI200987) | LIDOCAINE | 40 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K) | |
| OCTOXYNOL-9 (UNII: 7JPC6Y25QS) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:80684-150-00 | 148 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/03/2025 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M003 | 03/03/2025 | |

Labeler - Fourstar Group USA, Inc. (140099503)

Revised: 3/2025

Fourstar Group USA, Inc.