BACTINE MAX- lidocaine liquid WellSpring Pharmaceutical 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.

Bactine[®] Max Liquid Bandage

Active Ingredients (w/w)

Lidocaine 4%

Purpose

External Analgesic

Uses

For temporary relief of pain or discomfort in minor cuts, scrapes and burns.

Warnings

For external use only

Do not use

- If you are allergic to any of the ingredients
- in or near the eyes
- 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
- deep cuts
- animal bites
- serious burns

When using this product

• do not apply over raw surfaces or blistered areas

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days, or clear up and occur again within a few days

Keep out of reach of children

• If swallowed, call a poison control center or get medical help right away.

Directions

- adults and children 2 years of age and older:
- shake well
- clean the affected area and apply a small amount up to 3 times daily and let dry
- a second coating may be applied for extra protection
- children under 2 years of age: ask doctor prior to use

Other information

Store at room temperature

Inactive ingredients

acrylates copolymer, alcohol denat, ammonium acrylates copolymer, benzalkonium chloride, disodium deceth-6 sulfosuccinate, disodium EDTA, laureth-30, propanediol, sodium dehydroacetate, water

Questions?

1-844-241-5454 or Bactine.com

Distributed by:

*Germs commonly associated with skin infections.

Distributed by:

WellSpring Pharmaceutical Corporation Sarasota, FL 34243

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Bactine Max is FSA/HSA eligible.

PACKAGE LABEL. PRINCIPAL DISPLAY PANEL

New Bactine Max Liquid Bandage with Lidocaine Max Pain Relief Kills 99% of Germs Invisible Protection

| Relieves | Kills | Protects | | | |
|----------|-------|----------|--|--|--|
| NO STING | | | | | |
| SHAKE W | /ELL | | | | |



Back Panel

New

Bactine Max

Liquid Bandage with Lidocaine

SHAKE WELL

Bactine Max Liquid Bandage's unique formula provides maximum strength pain relief with LIDOCAINE, kills 99.9% of germs*, and protects hard-to-cover minor cuts and scrapes. This flexible bandage dries clear quickly and is breathable to maximize healing.

| BACTINE MAX | | | | | |
|--|-------------------|--------|--------------------------------------|---------|------------------|
| lidocaine liquid | | | | | |
| | | | | | |
| Product Information | | | | | |
| Product Type | HUMAN OTC DRUG | ltem (| Code (Source) | NDC:651 | 97-832 |
| Route of Administration | TOPICAL | | | | |
| | | | | | |
| Active Ingredient/Active | Moietv | | | | |
| Ingredie | Basis of Strength | | Strength | | |
| LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987) | | | LIDOCAINE HYDROCHLORIDE ANHYDROUS | | 4 g in 100 mL |
| | | | | | |

| Ir | nactive Ingr | edie | ents | | | | | | |
|--|------------------------|----------|--|-------------------------|--------------|-------------------------|-----------------------|----------|--|
| Ingredient Name | | | | | | | | Strength | |
| BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ1374NL9E) | | | | | | | | | |
| ALCOHOL (UNII: 3K9958V90M) | | | | | | | | | |
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) | | | | | | | | | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | | | | | | | | | |
| PROPANEDIOL (UNII: 5965N8W85T) | | | | | | | | | |
| LAURETH-30 (UNII: W9D845551A) | | | | | | | | | |
| SC | DDIUM DEHYDR | ROAC | ETATE (UNII: | 8W46YN971G) | | | | | |
| W | ATER (UNII: 059 | QF0K | (O0R) | | | | | | |
| | | | | | | | | | |
| Product Characteristics | | | | | | | | | |
| Color | | | | white | Score | | | | |
| Shape | | | | | Size | | | | |
| FI | avor | | | | Imprint Code | | | | |
| С | ontains | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| P | ackaging | | | | | | | | |
| # | Item Code | Packa | | kage Description | | Marketing Start Date | Marketing End Date | | |
| 1 | NDC:65197- 832-03 | 1 in | 1 BOX | | | 04/01/2022 | | | |
| 1 | | | 0 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| Marketing Information | | | | | | | | | |
| Marketing Applicat | | | Applicati | ion Number or Monograph | | Marketing Start | Marke | ting End | |
| Category | | Citation | | | Date | | ate | | |
| OTC monograph not part348 final | | part348 | | | 04/01/2022 | | | | |

Labeler - WellSpring Pharmaceutical Corporation (110999054)

Revised: 2/2022

WellSpring Pharmaceutical Corporation