MEDICAINE STING AND BITE- benzocaine swab James Alexander 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.

MEDICAINE STING® & BITE SWABS

Drug Facts

Active Ingredients (each swab)

Benzocaine USP (20%), L-Menthol USP (1%)

Purpose

analgesic

Uses

For temporary relief of pain and itching associated with insect bites and stings.

Warnings

For external use only

- do not use in the eyes or mouth
- not for prolonged use
- do not apply other medications to the same affected areas unless advised by a doctor

Stop use and ask a doctor if condition for this preparation is used persists, or if a rash or irritation or allergic reaction develops.

Keep out of reach of children. Not for use with children less than 2 years old without medical advice. If swallowed, get medical help immediately or contact a Poison Control Center right away.

Directions

Reverse cardboard sleeve then crush at dot between thumb and forefinger. Once solution has saturated tip, apply topically to the sting or bite. May be used on affected area(s) up to 4 times per day.

Other Information

Store at room temperature away from light.

Inactive Ingredients

D&C Green Dye #5, D&C Yellow Dye #10, FD&C Blue Dye #1, PEG 300 NF, Isopropyl Alcohol USP, Purified Water USP.

Questions?

Call 1-908-362-9266 Monday through Friday, 9:00am - 5:00pm e.s.t

DISPENSING SOLUTIONS®

JAMES ALEXANDER CORPORATION

Blairstown, NJ. (908) 362-9266

Product information and MSDS available on-line at:

www.james-alexander.com

Void of Aqueous

Packaging



MEDICAINE STING AND BITE

benzocaine swab

| Product Information | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:46414-2040 |
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|--|---------------------------|----------------------|
| Ingredient Name | Basis of Strength | Strength |
| BENZO CAINE (UNII: U3RS Y48 JW5) (Benzo caine - UNII: U3RS Y48 JW5) | BENZOCAINE | 0.12 g in 0.6 mL |
| MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (Menthol-UNII:L7T10EIP3A) | MENTHOL, UNSPECIFIED FORM | 0.006 g in 0.6 mL |
| | | |

| Inactive Ingredients | | | |
|--|----------|--|--|
| Ingredient Name | Strength | | |
| D&C GREEN NO. 5 (UNII: 8J6RDU8L9X) | | | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | | | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | | | |
| POLYETHYLENE GLYCOL 300 (UNII: 5655G9 Y8 AQ) | | | |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) | | | |
| WATER (UNII: 059QF0KO0R) | | | |

| Packaging | | | | |
|-----------|------------------|---|-----------------------------|---------------------------|
| 1 | # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| | NDC:46414-2040-3 | 6 mL in 1 CARTON; Type 0: Not a Combination Product | 11/15/1986 | |
| | | | | |

| Marketing Information | | | | |
|-------------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part348 | 11/15/1986 | | |
| | | | | |

Labeler - James Alexander Corporation (040756421)

Registrant - James Alexander Corporation (040756421)

| Establishment | | | | |
|-----------------------------|---------|-----------|-------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| James Alexander Corporation | | 040756421 | manufacture(46414-2040) | |

Revised: 1/2019 James Alexander Corporation