BLT 3- tetracaine ointment CENTURA PHARMACEUTICALS INC

ACTIVE INGREDIENT

Tetracaine 2%

PURPOSE

Topical Anesthetic

USES

For the temporary relief of pain and itching.

WARNINGS

- For external use only.
- Avoid contact with eyes or mucus membranes.
- Do not apply to open or damaged skin.
- If condition worsens or symptoms persist for more than seven days, discontinue use and consult physician.
- If pregnant or breast feeding, contact physician prior to use.
- Keep out of reach of children. If swallowed, contact Poison Control Center.
- Do not use if allergic to any ingredient in ointment.
- Do not use in large quantities, particularly over raw surfaces or blistered areas.

DIRECTIONS

Adults and children two-years of age or older: Apply to affected area not more than three to four times daily. Children under two-years of age: consult a physician.

OTHER INFORMATION

Store below 77° F (25° C). Avoid direct sunlight.

INACTIVE INGREDIENTS

Aqua (Deionized Water), PEG-8 Stearate, PEG-100 Stearate, PEG8, PEG-75, Methylisothiazolinone

KEEP OUT OF REACH OF CHILDREN

PACKAGE LABELING



tetracaine ointment

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:70372-729

Route of Administration TOPICAL

Active Ingredient/Active Moiety

| | Ingredient Name | Basis of Strength | Strength |
|---|--|--------------------------|--------------|
| ı | TETRACAINE (UNII: 0619F35CGV) (TETRACAINE - UNII:0619F35CGV) | TETRACAINE | 2 g in 100 g |

| Inactive Ingredients | | | | |
|---|----------|--|--|--|
| Ingredient Name | Strength | | | |
| WATER (UNII: 059QF0KO0R) | | | | |
| PEG-100 STEARATE (UNII: YD01N1999R) | | | | |
| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) | | | | |
| POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P) | | | | |
| METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA) | | | | |
| PEG-8 STEARATE (UNII: 2P9L47VI5E) | | | | |

| ı | P | Packaging | | | | | |
|---|---|----------------------|---|-------------------------|-----------------------|--|--|
| | # | Item Code | Package Description | Marketing Start Date | Marketing End Date | | |
| | | NDC:70372-729- 01 | 5 g in 1 POUCH; Type 0: Not a Combination Product | 10/30/2016 | | | |

| Marketing Information | | | |
|-----------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC Monograph Drug | M017 | 10/30/2016 | |
| | | | |

Labeler - CENTURA PHARMACEUTICALS INC (084921637)

Registrant - CENTURA PHARMACEUTICALS INC (084921637)

Revised: 2/2024 CENTURA PHARMACEUTICALS INC