TETRACYTE TOPICAL- tetracycline hydrochloride ointment WOUNDS PROS, LLC

Tetracyte Topical Ointment

Drug Facts

Active Ingredient (in each gram)

Tetracycline-HCL 30mg

Purpose

First Aid/Antibiotic

Indications

First aid to help prevent the risk of skin infection in minor cuts, scrapes, or burns.

Warnings

For external use only. May be harmful if swallowed.

Do not use if allergic to any ingredient listed on this label. Allergy Alert

Do not use

- in eyes
- over large areas of the body
- longer than 1 week unless directed by doctor

Ask a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious trauma

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

- clean the affected area
- apply a small amount of this product (an amount equal to the surface area of the tip of a finger) on the area 1 to 3 times daily

• may be covered with a sterile bandage

Stop use if product is misused

- this product is an OTC antibiotic for human use
- contains no alcohol, no animal ingredients
- blended for typical skin color
- may stain cloth
- no claims regarding stem cell healing are implied for this product

Other Information

• For best results refrigerate or store in a cool dark place.

Inactive Ingredients

acetic acid, ascorbic acid, chlorhexidine gluconate, cholecalciferol, dimethyl sulfoxide, dipropylene glycol, glucono delta lactone, glycerin, histidine, hydroxethyl-cellulose, magnesium stearate, sodium hydroxide, sorbic acid, stearic acid, water

Package Labeling:





TETRACYTE TOPICAL

tetracycline hydrochloride ointment

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:79790-000

Route of Administration TOPICAL

Active Ingredient/Active Moiety

| | Ingredient Name | Basis of Strength | Strength |
|---|---|--------------------------|----------|
| | TETRACYCLINE HYDROCHLORIDE (UNII: P6R62377KV) (TETRACYCLINE - | TETRACYCLINE | 30 mg |
| ı | UNII:F8VB5M810T) | HYDROCHLORIDE | in 1 mL |

| Inactive Ingredients | | |
|--|----------|--|
| Ingredient Name | Strength | |
| ACETIC ACID (UNII: Q40Q9N063P) | | |
| ASCORBIC ACID (UNII: PQ6CK8PD0R) | | |
| CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) | | |
| CHOLECALCIFEROL (UNII: 1C6V77QF41) | | |
| DIMETHYL SULFOXIDE (UNII: YOW8V9698H) | | |
| DIPROPYLENE GLYCOL (UNII: E107L85C40) | | |
| GLUCONOLACTONE (UNII: WQ29KQ9POT) | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | |
| HISTIDINE (UNII: 4QD397987E) | | |
| HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D) | | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | |
| SORBIC ACID (UNII: X045WJ989B) | | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | | |
| WATER (UNII: 059QF0KO0R) | | |

| F | Packaging | | | | | |
|---|----------------|--|-------------------------|-----------------------|--|--|
| # | tem Code | Package Description | Marketing Start Date | Marketing End Date | | |
| 1 | NDC:79790-000- | 1 in 1 BOX | 07/01/2020 | | | |
| 1 | | 15 mL in 1 BOTTLE; Type 0: Not a Combination Product | | | | |

| Marketing Information | | | | |
|-----------------------|---|-------------------------|-----------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC Monograph Drug | M004 | 07/01/2020 | | |
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Labeler - WOUNDS PROS, LLC (081422414)

Revised: 12/2023 WOUNDS PROS, LLC