

VITASTEM-TETRACYCLINE HYDROCHLORIDE- tetracycline hydrochloride spray
ViaDerma Distribution, Inc.

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.

Vitas tem-tetracycline hydrochloride spray

Drug Facts

Active Ingredient

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.

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

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.

Inactive Ingredients:

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

Package Labeling:



VITASTEM-TETRACYCLINE HYDROCHLORIDE

tetracycline hydrochloride spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71262-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
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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)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBIC ACID (UNII: X045WJ989B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71262-003-00	1 in 1 BOX	08/01/2019	
1		55 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	08/01/2019	

Labeler - ViaDerma Distribution, Inc. (081113521)