VITASTEM- tetracycline hydrochloride ointment 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.

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Drug Facts

Active Ingredient

Tetracycline-HCI 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 is 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:

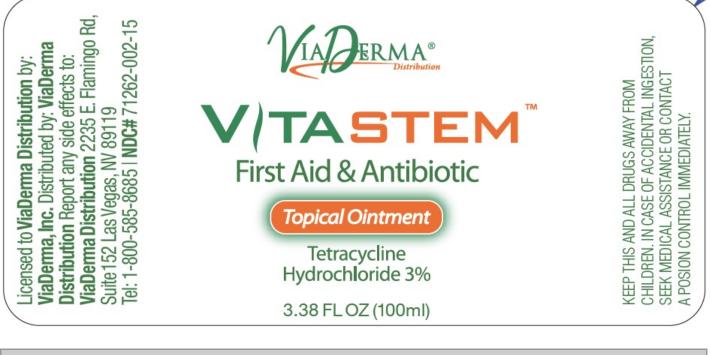


VITASTEM-tetracycline hydrochloride ointment, 60 ml (71262-002-01)



VITASTEM-tetracycline hydrochloride ointment, 100 ml (71262-002-02





tetracycline hydrochloride ointment

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71262-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
TETRACYCLINE HYDRO CHLO RIDE (UNII: P6R62377KV) (TETRACYCLINE - UNII:F8VB5M810T)	TETRACYCLINE HYDROCHLORIDE	30 mg in 1 mL		

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)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBIC ACID (UNII: X045WJ989B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

	ATER (UNII: 059QF0	ικουκ					
Pa	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:71262-002-00	1 in 1 BOX	02/09/2017				
1		5 mL in 1 BOTTLE; Type 0: Not a Combination Product					
2	NDC:71262-002-15	1 in 1 BOX	0 7/0 1/20 17				
2		15 mL in 1 BOTTLE; Type 0: Not a Combination Product					
3	NDC:71262-002-01	1 in 1 BOX	11/08/2016				
3		60 mL in 1 BOTTLE; Type 0: Not a Combination Product					
4	NDC:71262-002-02	1 in 1 BOX	11/08/2016				
4		100 mL in 1 BOTTLE; Type 0: Not a Combination Product					
Marketing Information							
	farketing Category		Marketing Start Date	Marketing End Date			
	FC monograph final		11/08/2016	marketing Line Date			

Labeler - ViaDerma Distribution, Inc. (081113521)

Revised: 3/2019

ViaDerma Distribution, Inc.