

DERMACLINE- tetracycline hydrochloride ointment
Inventus, LLC

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.

Dermacline

Active Ingredient (in each gram)

Tetracycline Hydrochloride 30mg

Purpose

First Aid antibiotic

Use

First aid to help prevent skin infection in minor cuts, scrapes, and burns.

Warnings

For esternam 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 our 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.

Other Information

- Keep product refrigerated to preserve its effectiveness and color
- 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 Ingredient

Acetic Acid, Ascorbic Acid, chlorhexidine gluconate, cholecalciferol, dimethyl sulfoxide, dipropylene glycol, glucono delta lactone, GLYCERIN, histidine, hydroxethylc-cellulose, magnesium stearate, methylparaben, sodium hydroxide, sorbic acid, steric acid, water.

Label- Dermacline Topical Ointment

Dermacline Topical ointment
Patent pending
Alcohol free, no biological products.

Drug Facts	
Active ingredient (in each gram)	Purpose
Tetracycline hydrochloride 30 mg	First Aid Antibiotic
Use First aid to help prevent skin infection in minor cuts, scrapes, and 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 the 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 burns	
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.	
Other information	
■ Keep product refrigerated to preserve its effectiveness and color ■ Stop use if product is misused: If the bottle is left open and/or if not refrigerated, the liquid will tend to turn black over time. Discard the product if the liquid turns black due to misuse. ■ 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, HYDROXYETHYL-CELLULOSE, MAGNESIUM STEARATE, METHYLPARABEN, SODIUM HYDROXIDE, SORBIC ACID, STEARIC ACID, WATER	

Side effects

Same as other tetracycline products.
Report any side effects to Inventus, LLC
17100 Bear Valley Rd, Suite 290, Victorville, CA 92395
dermacline.com
(213) 222-6949

DERMACLINE			
tetracycline hydrochloride ointment			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71250-002
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
ACETIC ACID (UNII: Q40Q9N063P)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
GLYCERIN (UNII: PDC6A3C0OX)	
HISTIDINE (UNII: 4QD397987E)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBIC ACID (UNII: X045WJ989B)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71250-002-00	1 in 1 BOX	02/09/2017	
1		5 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 final	part333B	11/08/2016	

Labeler - Inventus, LLC (080506784)**Establishment**

Name	Address	ID/FEI	Business Operations
Inventus, LLC		080506784	manufacture(71250-002)

Revised: 11/2016

Inventus, LLC