TETRANEXT- tetracycline hydrochloride ointment Saxet Pharmaceuticals

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.

TetraNextTM

Drug Facts

Active Ingredient

Tetracycline hydrochloride 3%

Purpose

First aid antibiotic ointment

Uses

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

Warnings

For external use only

Do not use

- in the eyes
- if you are allergic to any of the ingredients
- over large areas of the body
- Longer than 1 week unless directed by a physician

Ask a physician before use if you have

- deep or puncture wounds
- animal bites
- serious burns

Stop use and ask a physician if

- condition persists or gets worse
- rash or other allergic reaction occurs

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Clean the infected area
- Remove the twist cap from one vial
- Apply a small amount of this product (an amount equal to the surface area of the finger) on the area 1 to 3 times daily, or as directed by a physician
- Discard vial after use
- May be covered with a sterile bandage

Other Information

• Store at room temperature 20-25°C (68-77°F)

Inactive Ingredients

Water, glycerin, hydroxethylcellulose, chlor-hexide gluconate, glucono delta lactone, methylparaben, sodium hydroxide, dipropylene glycol, dimethyl sulfoxide, sorbic acid, ascorbic acid, magnesium stearate, stearic acid

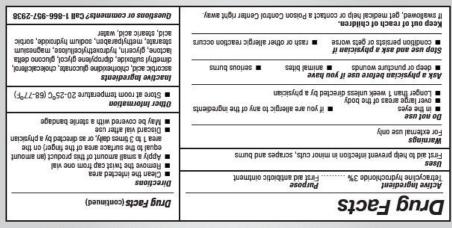
Questions or comments?

Call 1-866-957-2938

PRINCIPAL DISPLAY PANEL - 0.3 mL Vial Carton SAXET | PHARMACEUTICALS

 $TetraNext^{TM}$

Tetracycline HCl 3% | First Aid Ointment MAXIMUM INFECTION PROTECTION 20 single-use vials - 0.3 mL each NDC 70598-001-20



KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION









TETRANEXT

tetracycline hydrochloride ointment

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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70598-001
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	
Water (UNII: 059QF0KO0R)		
glycerin (UNII: PDC6A3C0OX)		
hydroxymethyl cellulose (UNII: 273FM27VK1)		
chlorhexidine gluconate (UNII: MOR84MUD8E)		
gluconolactone (UNII: WQ29KQ9POT)		
methylparaben (UNII: A2I8C7HI9T)		
sodium hydroxide (UNII: 55X04QC32I)		
dipropylene glycol (UNII: E107L85C40)		
dimethyl sulfoxide (UNII: YOW8V9698H)		
sorbic acid (UNII: X045WJ989B)		
ascorbic acid (UNII: PQ6CK8PD0R)		
magnesium stearate (UNII: 70097M6I30)		
stearic acid (UNII: 4ELV7Z65AP)		

Product Characteristics			
Color	BROWN (Light brown)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

1	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70598-001- 20	20 in 1 CARTON	08/01/2016	
1		0.3 mL in 1 BOTTLE, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:70598-001- 05	5 in 1 CARTON	08/01/2016	
2		$0.3\ mL$ in $1\ BOTTLE,\ UNIT-DOSE;\ Type\ 0$: Not a Combination Product		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part333B	08/01/2016		

Labeler - Saxet Pharmaceuticals (080032028)

Revised: 2/2017 Saxet Pharmaceuticals