DYABETEX - tetracycline hydrochloride ointment Phillips Company

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.

DRUG FACTS

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Active Ingredient Purpose

Tetracycline (3%) First-aid antibiotic

Uses

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

For external use only.

Keep away from children.

Do not use in the eyes or apply over large areas of the body.

May be harmful if swallowed.

In case of deep or puncture wounds, animal bites, or serious burns, consult a physician.

Stop use and consult a physician if the condition persists or gets worse. Do not use if allergic to any ingredient listed on this label.

Do not use longer than 1 week.

Discard this product 1 week after opening bottle.

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 and rub gently using a cotton swab. Repeat the process three times daily. Keep this product refrigerated to preserve effectiveness and color.

Other information

This product is an OTC antibiotic drug product for human use. This product contains no alcohol; no animal ingredients; no biological ingredients. Blended for typical skin color. May stain cloth.

Inactive ingredients

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

Side effects

Same as other tetracycline products. See listing of side effects online at www.PhillipsCompany.4T.com/CC.pdf Report any side effects to Phillips Company, 311 Chickasaw Street, Millerton, OK USA 74750 Tel. 580-746-2430.

Email: PhillipsCompany@cox.net

Active Ingredient		Purpose	
Tetracycline (3%))	First-aid antibioti	C

ASK DOCTOR

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In case of deep or puncture wounds, animal bites, or serious burns, consult a physician. Stop use and consult a physician if the condition persists or gets worse.

DO NOT USE

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Do not use longer than 1 week. Discard this product 1 week after opening bottle.

CHILDREN

Keep away from children.

Discard this product 1 week after opening bottle.

PURPOSE

Active Ingredient	Purpose
Tetracycline (3%)	First-aid antibiotic

STOP USE

Stop use and consult a physician if the condition persists or gets worse.

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

Do not use longer than 1 week. Discard this product 1 week after opening bottle.

WHEN USING

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

In case of deep or puncture wounds, animal bites, or serious burns, consult a physician.

WARNINGS

Side effects: same as other tetracycline products. See listing of side effects online at www.PhillipsCompany.4T.com/CC.pdf

Report any side effects to Phillips Company, 311 Chickasaw Street, Millerton, OK USA 74750 Tel. 580-746-2430. Email: PhillipsCompany@cox.net

DOSAGE & ADMINISTRATION

Directions

Clean the affected area. Apply 2 drops of this liquid on the affected area about the size of a nickel or dime, and rub gently using a cotton swab. For international users, a nickel or a dime is approximately 1.5 square centimeters. Repeat the process three times daily. Keep this product refrigerated to preserve effectiveness and color.

USE

Uses

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

For external use only.

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May be harmful if swallowed.

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Stop use and consult a physician if the condition persists or gets worse. Do not use if allergic to any ingredient listed on this label.

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INACTIVE INGREDIENTS

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Image of product

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DYABETEX

tetracycline hydrochloride ointment

Product Type HUMAN OTC DRUG	Item Code (Source)	NDC:43074-108
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Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength TETRACYCLINE HYDROCHLORIDE (UNII: P6 R6 2377KV) (TETRACYCLINE - UNII: F8 VB5M8 10 T) TETRACYCLINE D0.03 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
dipropylene glycol (UNII: E107L85C40)		
Water (UNII: 059QF0KO0R)		
glycerin (UNII: PDC6A3C0OX)		
CHLORHEXIDINE GLUCONATE (UNII: MOR8 4MUD8 E)		
calcium gluconate (UNII: SQE6VB453K)		
methylparaben (UNII: A2I8C7HI9T)		
sodium hydroxide (UNII: 55X04QC32I)		
sorbic acid (UNII: X045WJ989B)		
magnesium stearate (UNII: 70097M6I30)		
stearic acid (UNII: 4ELV7Z65AP)		
CHOLECALCIFEROL (UNII: 1C6V77QF41)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:43074-108-02	1 in 1 BOTTLE, PLASTIC		
1 NDC:43074-108-01	3 mL in 1 BOTTLE, DROPPER		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	08/24/2010	

Labeler - Phillips Company (612368238)

Establishment				
Name	Address	ID/FEI	Business Operations	
Phillips Company		612368238	manufacture	

Revised: 9/2010 Phillips Company