

## **ACNECYCLINE - 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.*

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### **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.

##### 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. If not completely rubbed in after a 20-second rub-in, too much product was used. 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. 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](http://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](mailto:PhillipsCompany@cox.net)

### **ACTIVE INGREDIENTS**

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

## **ASK DOCTOR**

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**

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

## **CHILDREN**

Keep away from children.

## **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.

## **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](http://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](mailto:PhillipsCompany@cox.net)

## **DOSAGE & ADMINISTRATION**

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. If not completely rubbed in after a 20-second rub-in, too much product was used. Repeat the process three times daily. For best results, refrigerate this product to reduce oxidation rate; to preserve effectiveness and color (normally orange). Discard this product if color turns black.

## **USE**

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.

## **INACTIVE INGREDIENTS**

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

## **Image of product**



## ACNECYCLINE

tetracycline hydrochloride ointment

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:43074-116
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TETRACYCLINE HYDROCHLORIDE (UNII: P6R62377KV) (TETRACYCLINE - UNII:F8VB5M810T)	TETRACYCLINE	0.03 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)	

<b>ascorbic acid</b> (UNII: PQ6CK8PD0R)
<b>dipropylene glycol</b> (UNII: E107L85C40)
<b>Water</b> (UNII: 059QF0KO0R)
<b>glycerin</b> (UNII: PDC6A3C0OX)
<b>CHLORHEXIDINE GLUCONATE</b> (UNII: MOR84MUD8E)
<b>calcium gluconate</b> (UNII: SQE6VB453K)
<b>methylparaben</b> (UNII: A2I8C7HI9T)
<b>sodium hydroxide</b> (UNII: 55X04QC32I)
<b>sorbic acid</b> (UNII: X045WJ989B)
<b>magnesium stearate</b> (UNII: 70097M6I30)
<b>stearic acid</b> (UNII: 4ELV7Z65AP)
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43074-116-02	1 in 1 BOTTLE, PLASTIC		
1	NDC:43074-116-01	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	02/15/2011	

**Labeler** - Phillips Company (612368238)

### Establishment

Name	Address	ID/FEI	Business Operations
Phillips Company		612368238	manufacture