

# SCHEIN TRIPLE ANTIBIOTIC- neomycin sulfate, polymyxin b sulfate, bacitracin zinc ointment

## Henry Schein, 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.*

### DRUG FACTS

**Active Ingredients: In each gram-Neomycin Sulfate-5 mg (equivalent to 3.5 mg Neomycin), Polymyxin B Sulfate-5000 I.U., Bacitracin Zinc-400 I.U.**

PURPOSE: First aid antibiotic

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

For external use only. Do not use on eyes. Do not use if you are allergic to any of the ingredients due to the possibility of anaphylactic shock.

Stop use and ask a doctor before use in cases of deep puncture wounds, animal bites, serious burns; if the condition persists or gets worse; if a rash or other allergic reaction develops

If swallowed get medical help or contact a poison control center right away

KEEP OUT OF THE REACH OF CHILDREN

Clean the affected area. apply a small amount of product ( an amount equal to the surface area of the tip of a finger) on the area 1-3 times daily. May be covered with a sterile bandage.

INACTIVE INGREDIENT: WHITE PETROLATUM

Bacitracin Zinc 400 units  
Neomycin Sulfate 5mg  
Polymyxin B Sulfate 5000 units  
144 Packets/Net Wt. 0.9 grams  
Reorder #900-4788



HENRY SCHEIN® TRIPLE ANTIBIOTIC	
<b>Drug Facts</b>	<b>Drug Facts (continued)</b>
<b>Active Ingredients (in each gram)</b> Bacitracin Zinc 400 units Neomycin Sulfate 5mg (equivalent to 3.5 mg Neomycin Base) Polymyxin B Sulfate 5000 units	<b>Purpose(s)</b> First aid to help prevent infection in minor cuts, scrapes and burns. <b>Warnings</b> Do not use: • If you are allergic to any of the ingredients, due to the possibility of anaphylactic shock. • On deep puncture wounds of the body. • Longer than 1 week unless directed by a doctor. • On the face or near the eyes. • In the case of deep puncture wounds, animal bites or serious burns.
<b>Directions</b> Apply to the affected area. Apply a small amount of the product (an amount equal to the surface area of the tip of a finger) on the area 1-3 times daily. Keep the area covered with a sterile bandage.	<b>Other Information</b> • Keep container tightly closed to keep ointment from drying out or becoming rancid. • Store at controlled room temperature (15° to 30°C/59° to 86°F). • See back of container for full directions. <b>Contains inactive ingredients: white petrolatum.</b>
<b>Questions or Comments:</b> 1-800-474-4344	



NDC #0404-0360-47



Made in USA  
Reorder #900-4788  
Rev. 02-15

# SCHEIN TRIPLE ANTIBIOTIC

neomycin sulfate, polymyxin b sulfate, bacitracin zinc ointment

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0404-0360
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>NEOMYCIN SULFATE</b> (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN	3.5 mg in 1 g
<b>POLYMYXIN B SULFATE</b> (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ.07J96K)	POLYMYXIN B	5000 [iU] in 1 g
<b>BACITRACIN ZINC</b> (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	400 [iU] in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0404-0360-47	144 in 1 BOX	04/21/2015	
1	NDC:0404-0360-09	0.9 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:0404-0360-48	1 in 1 CARTON	04/21/2015	
2	NDC:0404-0360-28	28 g in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M004	04/21/2015	03/01/2024

**Labeler** - Henry Schein, Inc. (012430880)

**Registrant** - Ultraseal Corporation (085752004)

## Establishment

Name	Address	ID/FEI	Business Operations
Ultra Seal Corporation		085752004	pack(0404-0360)

## Establishment

Name	Address	ID/FEI	Business Operations
ULTRAtab Laboratories, Inc.		151051757	manufacture(0404-0360)

## Establishment

Name	Address	ID/FEI	Business Operations
Ultra Seal Corporation		944090448	pack(0404-0360)

Revised: 1/2023

Henry Schein, Inc.