

AEROSOOTHE- triple antibiotic ointment ointment
Aero Healthcare US 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.

AEROSOOTHE TRIPLE ANTIBIOTIC OINTMENT

ACTIVE INGREDIENT

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

Purpose

First Aid Antibiotic

Warnings:

For external use only.

Do not use:

- in eyes
- over large areas of the body or on puncture wounds, animal bites or serious burns
- for more than 1 week unless directed by a doctor
- if you are allergic to any of the ingredients due to anaphylactic shock

KEEP OUT OF REACH OF CHILDREN

KEEP OUT OF REACH OF CHILDREN.

IF INGESTED, CONTACT A POISON CONTROL CENTER RIGHT AWAY.

DIRECTIONS

- CLEAN AFFECTED AREA
- APPLY A SMALL AMOUNT 1 TO 3 TIMES DAILY
- MAY COVER WITH A STERILE BANDAGE

INACTIVE INGREDIENT

INACTIVE INGREDIENT: WHITE PETROLATUM

Indications & Usage

FIRST AID TO HELP PREVENT INFECTION IN MINOR SCRAPES, CUTS AND BURNS.

AST05USV2

AERO SOOTHE Triple ANTIBIOTIC OINTMENT 0.5g	
Manufactured for: AERO HEALTHCARE US Valley Cottage, NY, 10989 www.aerohealthcare.us.com ASTA05US	
DRUG FACTS: ACTIVE INGREDIENTS PURPOSE (in each gram) Bacitracin Zinc 400 units Neomycin Sulfate 5mg (equivalent to 3.5mg Neomycin) Polymyxin B Sulfate 5000 units. First Aid Antibiotics	
USES: First aid to help prevent infection in minor scrapes, cuts and burns	
WARNINGS: For external use only	
DRUG FACTS (CONTINUED): WARNINGS (continued): Do not use in eyes or over large areas of the body or on puncture wounds, animal bites or serious burns for more than 1 week unless directed by a doctor if you are allergic to any of the ingredients due to anaphylactic shock	
Stop use and ask a doctor if: a rash or allergic reaction develops condition worsens or persists	
Keep out of reach of children. If ingested, contact a Poison Control Centre right away.	
DIRECTIONS: Clean affected area apply a small amount 1 to 3 times daily may cover with a sterile bandage	
INACTIVE INGREDIENT: White petrolatum	



CODE:
V2.ASTA05US.POU

DATE:
06/20/2019

DIMENSIONS:
33mm W x 64mm H

AEROSOOTHE

triple antibiotic ointment ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55305-123
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ.07J96K)	POLYMYXIN B	5000 [iU] in 1 g
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	400 [iU] in 1 g
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN	5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55305-123-02	25 in 1 BOX	02/01/2016	
1	NDC:55305-123-01	0.9 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:55305-123-03	0.5 g in 1 PACKET; Type 0: Not a Combination Product	10/20/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	10/20/2015	

Labeler - Aero Healthcare US LLC (008186174)

Revised: 3/2023

Aero Healthcare US LLC