

TRIPLE ANTIBIOTIC- bacitracin zinc neomycin sulfate polymyxin b sulfate ointment

NuCare Pharmaceuticals, 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.

Triple Antibiotic Ointment-Bacitrazcin, Neomycin and Polymycin

Active ingredients (in each gram)

Bacitracin zinc, USP 400 units

Neomycin 3.5 mg

Polymyxin B Sulfate, USP 5,000 units

Purpose

First aid antibiotic

Uses

First aid to helps prevent infection in

- minor cuts
- scrapes
- burns

Warnings

For external use only

Allergy alert:

- do not use if allergic to any of the ingredients

Do not use

- in the eyes
- over large areas of the body

Ask a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burns

When using this product

- do not use longer than 1 week unless directed by a doctor

Stop use and ask a doctor if

- condition persists or gets worse
- a rash or other allergic reaction develops

Keep out of reach of children.

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

Directions

- clean 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 1 to 3 times daily
- may be covered with a sterile bandage

Other Information

- Store at controlled room temperature 59°-86°F (15°-30°C). Protect from freezing.
- Before using any medication, read all label directions. Keep carton, it contains important information.

Inactive ingredient

white petrolatum

Questions?

1-800-432-8534 between 9 am and 4 pm EST, Monday-Friday.

PRINCIPAL DISPLAY PANEL

NDC: 68071-3378-5

**Triple Antibiotic
0.5oz Ointment**

Bacitracin zinc, USP 400 units
Neomycin 3.5mg
Polymyxin B sulfate, USP 5,000
units. See manufacturer's label
for full list of ingredients.

Product #: R0350015

Triple Antibiotic

Lot: 000000 NDC: 68071-3378-05
MFR NDC: 0472-0179-34 Exp.: 00-00
Serial# 00000000002

Triple Antibiotic

Lot: 000000 NDC: 68071-3378-05
MFR NDC: 0472-0179-34 Exp.: 00-00
Serial# 00000000002



GTIN 00368071337853
Serial# 00000000002
Exp. Date 00-00
LOT#: 000000

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Distributed by: 3 68071337853
Actavis Pharma, Inc. Parsippany, NJ
07054
Packaged By:
NuCare Pharmaceuticals, Inc.
Orange, CA 92867
Patient Instructions:
Apply every _____ hours
_____ times a day.



Rev 01/01/19
WARNING: KEEP OUT OF REACH OF CHILDREN

STORE AT CONTROLLED TEMPERATURE 59-86°F.

TRIPLE ANTIBIOTIC

bacitracin zinc neomycin sulfate polymyxin b sulfate ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68071-3378(NDC:0472-0179)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-3378-5	15 g in 1 BOX; Type 0: Not a Combination Product	07/18/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	01/01/2003	

Labeler - NuCare Pharmaceuticals, Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals, Inc.		010632300	relabel(68071-3378)

Revised: 2/2021

NuCare Pharmaceuticals, Inc.