

CARING MILLS TRIPLE ANTIBIOTIC- bacitracin zinc, neomycin sulfate, and polymyxin b sulfate ointment
Veridian Healthcare

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.

Caring Mills Triple Antibiotic Ointment

Active Ingredients

- Bacitracin zinc
- Neomycin sulfate
- Polymyxin B Sulfate

Active ingredients (in each gram)	Purpose
Bacitracin 400 units	First aid antibiotic
Neomycin 3.5 mg	First aid antibiotic
Polymyxin B 5,000 units	First aid antibiotic

Use

first aid to help prevent infection in minor:

- cuts
- scrapes
- burns

Warnings

For external use only.

Do not use

- if you are allergic to any of the ingredients
- 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

use only as directed

Stop use and ask a doctor if

- you need to use longer than 1 week
- condition persists or gets worse
- 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.(1-800-222-1222)

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

Other information

- store at 20° to 25°C (68° to 77° F)
- do not use if tube seal under cap is broken

Inactive ingredients

alpha-tocopherol acetate, cocoa butter, cottonseed oil, light mineral oil, olive oil, paraffin, petrolatum, sodium pyruvate

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71101-801
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	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	3.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
PARAFFIN (UNII: I9O0E3H2ZE)	
COCOA BUTTER (UNII: 512OYT1CRR)	
COTTONSEED OIL (UNII: H3E878020N)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
SODIUM PYRUVATE (UNII: POD38AIF08)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71101-801-01	1 in 1 CARTON	05/01/2023	
1		56.6 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	part333B	05/01/2023	

Labeler - Veridian Healthcare (830437997)

Establishment

Name	Address	ID/FEI	Business Operations
ANICARE PHARMACEUTICALS PRIVATE LIMITED		916837425	manufacture(71101-801)

Revised: 5/2023

Veridian Healthcare