

ASTONEA FIRST AID- bacitracin zinc neomycin sulfate polymyxin b sulfate ointment

ASTONEA LABS PRIVATE LIMITED

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.

ASTONEA Triple Antibiotic

***Active ingredients
(in each gram)***

Bacitracin Zinc 400 units

Neomycin Sulfate 5 mg (Equivalent to 3.5 mg Neomycin)

Polymyxin B sulfate 5000 units

Purpose

First Aid Antibiotic First Aid Antibiotic First Aid Antibiotic

Uses

■ first aid to help prevent infection in ■ minor cuts ■ scrapes ■ burns

Warnings

For external use only

Do not use

■ in the eyes ■ if you are allergic to any of the ingredients ■ over large areas of the body ■ longer than 1 week unless directed by a doctor

Ask a physician before use in case of

■ deep or puncture wounds ■ animal bites ■ serious burns

Stop use and consult a doctor if

■ the 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 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 room temperature 15-30C (59-86F) ■ avoid excessive heat and humidity ■ Tamper evident ■ Do not use if packet is cut, torn or opened

Inactive ingredients

white petrolatum

Package Label



ASTONEA FIRST AID

bacitracin zinc neomycin sulfate polymyxin b sulfate ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77338-302
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	400 [USP'U] 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 [USP'U] in 1 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77338-302-53	0.9 g in 1 PACKET; Type 0: Not a Combination Product	05/02/2022	
2	NDC:77338-302-54	28.3 g in 1 TUBE; Type 0: Not a Combination Product	05/02/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	05/02/2022	

Labeler - ASTONEA LABS PRIVATE LIMITED (878533295)

Registrant - ASTONEA LABS PRIVATE LIMITED (878533295)

Revised: 8/2022

ASTONEA LABS PRIVATE LIMITED