ASTONEA FIRST AID- bacitracin zinc 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 Bacitracin Zinc

Active Ingredient (in each gram)

Bacitracin Zinc (equal to 500 bacitracin units)

Purpose

First Aid Antibiotic

Uses

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

Warnings

For external use only

Do not use

■ Not for opthalmic use **Do not use** \blacksquare in the eyes \blacksquare if you are allergic to any of the ingredients, due to possibility of anaphylactic shock \blacksquare over large areas of the body \blacksquare longer than 1 week unless directed by a doctor

Ask a doctor before use in case of

- deep or puncture wounds
- animal bites serious burns

Stop use and ask a doctor if

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

Keep out of reach of children

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

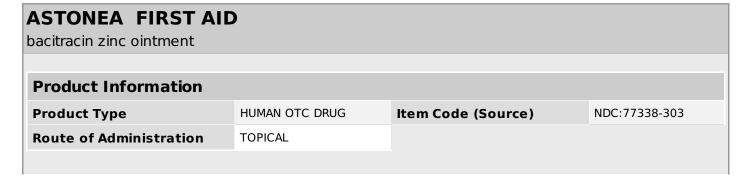
- store at room temperature 15-30C (59-86F)
- avoid excessive heat and humidity

Inactive Ingredients

hard paraffin, liquid paraffin, white soft paraffin, lanolin

Package Label





Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RW052I)	BACITRACIN	500 [USP'U] in 1 g	

Inactive Ingredients				
Ingredient Name	Strength			
PARAFFIN (UNII: 1900E3H2ZE)				
MINERAL OIL (UNII: T5L8T28FGP)				
PETROLATUM (UNII: 4T6H12BN9U)				
LANOLIN (UNII: 7EV65EAW6H)				

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:77338-303- 52	0.9 g in 1 PACKET; Type 0: Not a Combination Product	05/02/2022		
2	NDC:77338-303- 53	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)

Establishment				
Name	Address	ID/FEI	Business Operations	
ASTONEA LABS PRIVATE LIMITED		878533295	manufacture(77338-303)	

Revised: 8/2022 ASTONEA LABS PRIVATE LIMITED