

ASTONEA FIRST AID- bacitracin zinc ointment
ASTONEA LABS PRIVATE LIMITED

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 ophthalmic use **Do not use** ■ in the eyes ■ if you are allergic to any of the ingredients, due to possibility of anaphylactic shock ■ over large areas of the body ■ 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

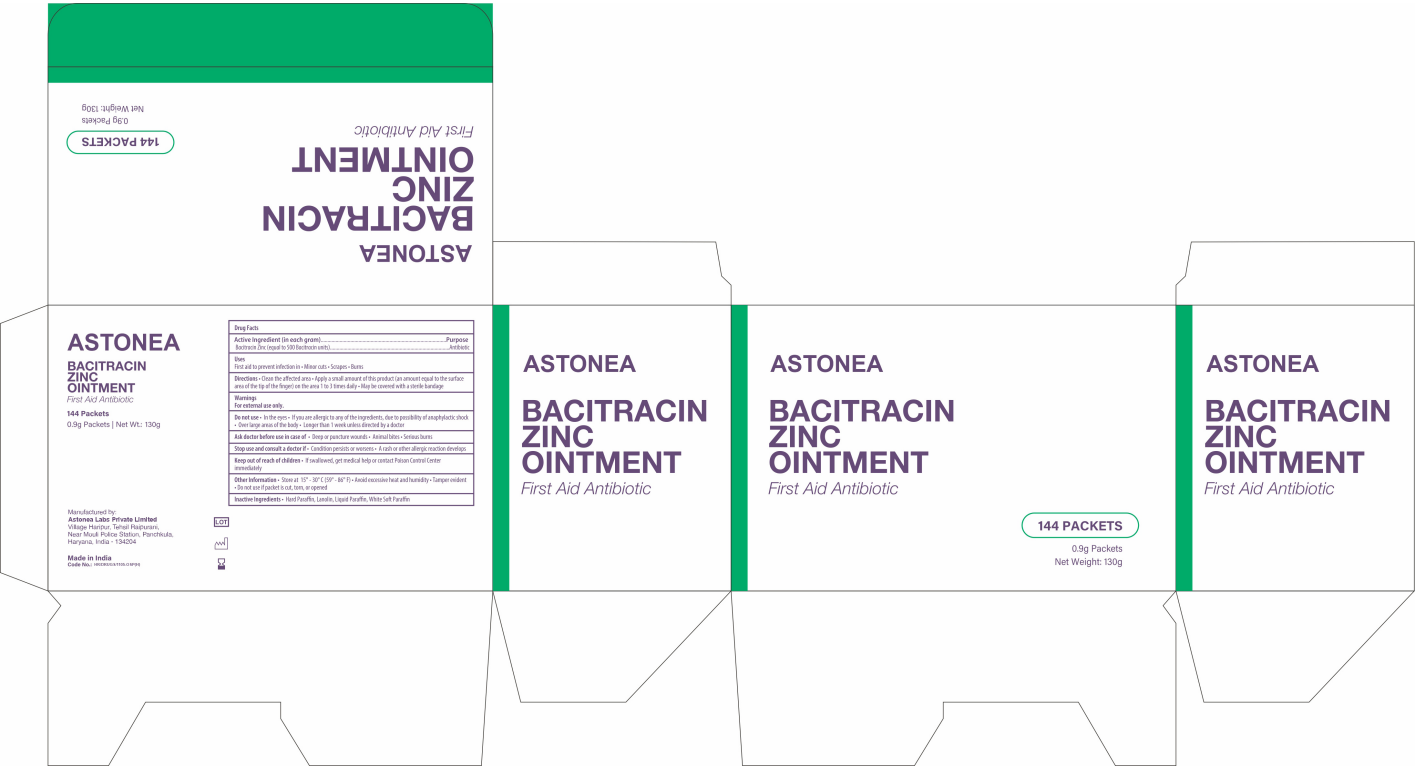
Other Information

- 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



ASTONEA FIRST AID

bacitracin zinc ointment

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77338-303
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength

BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	500 [USP'U] in 1 g
--	------------	--------------------

Inactive Ingredients	
Ingredient Name	Strength
PARAFFIN (UNII: I9O0E3H2ZE)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
LANOLIN (UNII: 7EV65EAW6H)	

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 Drug	M004	05/02/2022	

Labeler - ASTONEA LABS PRIVATE LIMITED (878533295)

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