

**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.*

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**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

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77338-303
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>BACITRACIN ZINC</b> (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	500 [USP'U] in 1 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>PARAFFIN</b> (UNII: I9O0E3H2ZE)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>LANOLIN</b> (UNII: 7EV65EAW6H)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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**

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

**Labeler** - ASTONEA LABS PRIVATE LIMITED (878533295)**Establishment**

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

Revised: 8/2022

ASTONEA LABS PRIVATE LIMITED