BACITRACIN ZINC- bacitracin zinc ointment
Dynarex Corporation

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.

Bacitracin Zinc Ointment

Active ingredient	**Purpose**
Bacitracin Zinc (500 Units in each gram)	First Aid Antibiotic

Warnings:

For external use only

DOSAGE & ADMINISTRATION:

- clean the affected areas, Apply a small amount of product (an amount equal to the surface area of the tip of the finger) on the area 1 to 3 times daily. May be covered with a sterile bandage

Stop use and ask a doctor if

Stop use and ask a doctor if the condition persists or gets worse, or if a rash or other allergic reaction develops.

Indications & Usage:

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

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

Purpose:

First aid to help prevent infection in minor cuts, scrapes, and burns.

Other information

- store at controlled room temperature
- Avoid excessive heat and humidity
- Tamper Evident. Do not use if inner seal is torn, cut or open.

Ask a doctor if

Ask a doctor before use if you have deep or puncture wounds, animal bites, or serious burns.

Inactive ingredients

Hard Paraffin, Liquid Paraffin, White Soft Paraffin

Principal Display Panel

Dynarex Bacitracin Zinc Ointment:

1175 ESG.jpg

BACITRACIN ZINC

bacitracin zinc ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67777-220
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**
PETROLATUM (UNII: 4T6H12BN9U)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	

MINERAL OIL (UNII: T5L8T28FGP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-220-02	28.35 g in 1 TUBE; Type 0: Not a Combination Product	12/01/2009	
2	NDC:67777-220-03	14.17 g in 1 TUBE; Type 0: Not a Combination Product	12/01/2009	
3	NDC:67777-220-04	113.4 g in 1 TUBE; Type 0: Not a Combination Product	12/01/2009	
4	NDC:67777-220-07	425.3 g in 1 JAR; Type 0: Not a Combination Product	12/01/2009	
5	NDC:67777-220-05	0.5 g in 1 PACKET; Type 0: Not a Combination Product	12/01/2009	
6	NDC:67777-220-01	0.9 g in 1 PACKET; Type 0: Not a Combination Product	12/01/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	12/01/2009	

Labeler - Dynarex Corporation (008124539)

Registrant - Dynarex Corporation (008124539)

Establishment

Name	Address	ID/FEI	Business Operations
Galentic Pharma (India) Pvt. Ltd.		864201135	manufacture(67777-220)

Establishment

Name	Address	ID/FEI	Business Operations
Galentic Pharma (India) Private Limited		650970176	manufacture(67777-220)

Revised: 6/2017 Dynarex Corporation