BACITRACIN- bacitracin 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.

1162_1163_Bacitracin_Ointment

Active ingredient	**Purpose**
Bacitracin 500 Units	Antibiotic

Warnings:

For external use only

Dosage and 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
- the condition persists or gets worse, or if a rash or other allergic reaction develops.

Do not use:
- if you are allergic to any of the ingredients
- in the eyes
- over large areas of the body
- longer than 1 week unless directed by a doctor

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
burns

Indications and Usage

Ask a doctor before use:
- in case of deep or puncture wounds
- animal bites
- serious burns

Other information
- store at controlled room temperature 15°-30° C (59°-86° F)

Inactive ingredients

Light Mineral Oil, White Petrolatum

Principal Display Panel

Bacitracin Ointment:

bacitracin-galentic-ointment-01.jpg

BACITRACIN

bacitracin ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67777-219
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BACITRACIN (UNII: 58H6RWO52I) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	500 [iU] in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:67777-219-01	72 in 1 CASE		
1		28.35 g in 1 TUBE		
2	NDC:67777-219-04	72 in 1 CASE		
2		14.17 g in 1 TUBE		
3	NDC:67777-219-06	12 in 1 CASE		
3		144 in 1 BOX		
3		0.5 g in 1 PACKET		
4	NDC:67777-219-07	12 in 1 CASE		
4		144 in 1 BOX		

4		0.9 g in 1 PACKET		
5	NDC:67777-219-05	72 in 1 CASE		
5		56.7 g in 1 TUBE		
6	NDC:67777-219-02	72 in 1 CASE		
6		113.4 g in 1 TUBE		
7	NDC:67777-219-03	12 in 1 CASE		
7		425.3 g in 1 JAR		

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)

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