REFILL 2- benzalkonium chloride, bacitracin zinc, neomycin sulfate, polymyxin b sulfate CMC Group, Inc.

Refill 2

Drug Facts - Antiseptic Towelettes

Active Ingredient:

Benzalkonium Chloride 0.13%

Purpose:

First Aid Antiseptic

Use:

For Professional and Hospital use. Helps prevent infection. Antiseptic cleansing of face, hands and body without soap and water.

Warnings:

For external use only.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away. If unusual redness, swelling or other symptoms occur, consult a physician immediately.

Do not use:

In the eyes, or over large areas of the body.

Directions:

Tear open packet, unfold towelette and use to cleanse desired skin area. Discard towelette appropriately after single use.

Inactive ingredient:

Purified water.

Drug Facts - Antibiotic Application

Active ingredients (in each gram)

Bacitracin zinc (bacitracin 400 units) Neomycin sulfate (neomycin 3.5mg) Polymyxin B sulfate (polymyxin B 5,000 units)

Purpose

First aid antibiotic

Use

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

Warnings

For external use only

Do not use

• in the eyes • over large areas of the body • if you are allergic to any of the ingredient • longer than 1 week unless directed by a doctor.

Ask a doctor before use if you have

• deep or punture 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.

If swallowed, get medical help or contact a Poison Control Center right away.

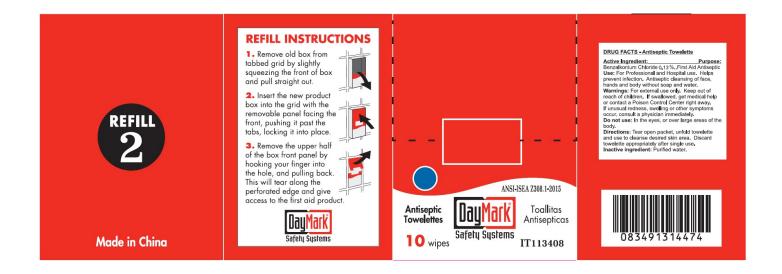
Directions

• 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.

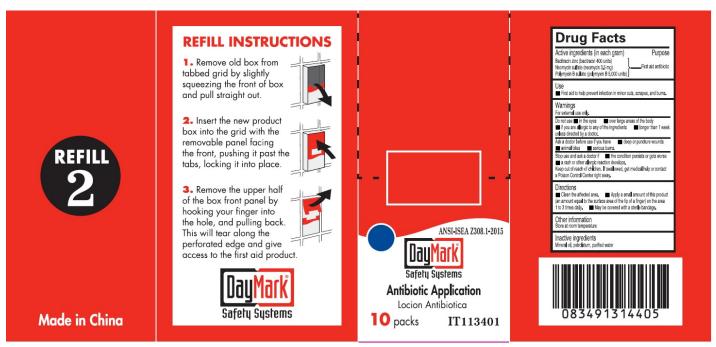
Inactive ingredients

Mineral oil, petrolatum, purified water

Antiseptic Towelettes (49687-0016-0) Labeling:



Antibiotic Application (49687-0013-0) Labeling:



Refill 2 (49687-0016-0) Labeling:



This box contains these items:





I131989

(1 box) IT113412 - Burn Relief (6 packs/box)

Quemadura de Socorro

(2 boxes) IT113408 - Antiseptic Towelettes (10 wipes/box)

Toallitas Antisepticas

(1 box) IT113401 - Antibiotic Application (10 packs/box)

Locion Antibiotica

REFILL 2

benzalkonium chloride, bacitracin zinc, neomycin sulfate, polymyxin b sulfate kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:49687-0016

Packaging

#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49687-0016-0	1 in 1 KIT	08/10/2016	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	20 PATCH	18 g
Part 2	10 PACKAGE	9 g

Part 1 of 2

ANTISEPTIC TOWELETTES

benzalkonium chloride cloth

Product Information

Item Code (Source)

NDC:49687-0011

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6IUD5X6Y)	BENZ ALKONIUM CHLORIDE	0.13 g in 100 a

Inactive Ingredients				
Ing	gredient Name	Strength		
WATER (UNII: 059QF0KO0R)				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1		2 in 1 BOX			
1	NDC:49687- 0011-1	10 in 1 BOX			
1		0.9 g in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)			

Marketing Information					
Marketing Category	Marketing End Date				
OTC Monograph Drug	M003	08/10/2016			

Part 2 of 2

ANTIBIOTIC APPLICATION

bacitracin zinc, neomycin sulfate, polymyxin b sulfate ointment

Product Information

Item Code (Source)	NDC:49687-0013
Route of Administration	TOPICAL

Active	Ingred	lient/Ad	ctive M	loiety
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Ingredient Name	Basis of Strength	Strength

BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RW052I)	BACITRACIN	400 [iU] in 1 g
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:116QD7X297)	NEOMYCIN	3.5 mg in 1 g
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII: J2VZ 07J96K)	POLYMYXIN B	5000 [iU] in 1 g

Inactive Ingredients				
Ingredient Name	Strength			
MINERAL OIL (UNII: T5L8T28FGP)				
PETROLATUM (UNII: 4T6H12BN9U)				
WATER (UNII: 059QF0KO0R)				

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:49687- 0013-0	10 in 1 KIT				
1	0.9 g in 1 PACKAGE; Type 0: Not a Combination Product				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M004			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	part333	08/10/2016		

Labeler - CMC Group, Inc. (117201448)

Revised: 12/2023 CMC Group, Inc.