REFILL 2- benzalkonium chloride, bacitracin zinc, neomycin sulfate, polymyxin b sulfate
GFA Production (Xiamen) Co., Ltd.

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.

Refill 2

Drug Facts

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.

Other information

Store at room temperature

Inactive ingredients

Mineral oil, petrolatum, purified water

DRUG FACTS

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.

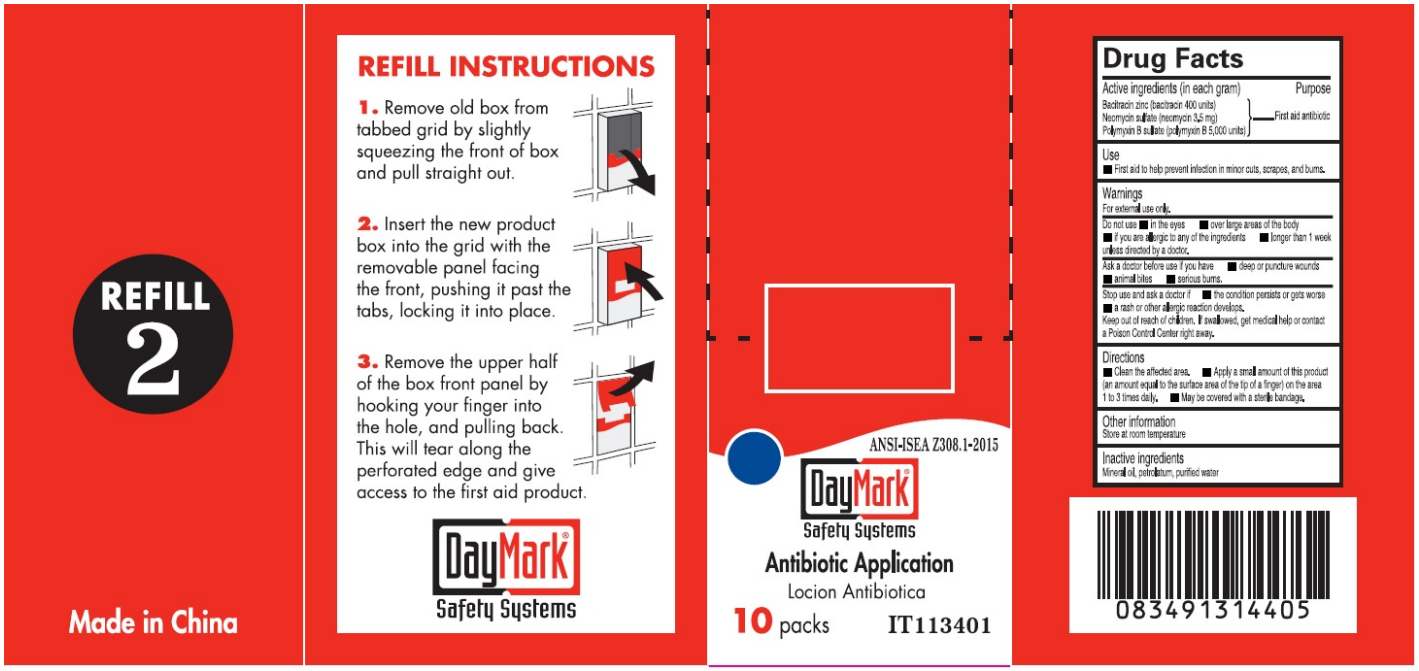
Directions:

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

Inactive ingredient:

Purified water.

Antibiotic Application (50814-013-01) Labeling:



Antiseptic Towelettes (50814-011-01) Labeling:

Refill 2 (50814-016-01) Labeling:

REFILL 2

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

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50814-016

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:50814-016-01	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 PACKET	9 g

Part 1 of 2

ANTISEPTIC TOWELETTES

benzalkonium chloride cloth

Product Information	
Item Code (Source)	NDC:50814-011
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:50814-011-01	2 in 1 BOX		
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	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/10/2016	

Part 2 of 2

ANTIBIOTIC APPLICATION

bacitracin zinc, neomycin sulfate, polymyxin b sulfate ointment

Product Information	
Item Code (Source)	NDC:50814-013
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	400 [iU] in 1 g
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN	3.5 mg in 1 g
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	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:50814-013-01	1 in 1 BOX		
1		10 in 1 BOX		
1		0.9 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	08/10/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	08/10/2016	

Labeler - GFA Production (Xiamen) Co., Ltd. (421256261)

Establishment

Name	Address	ID/FEI	Business Operations
GFA Production (Xiamen) Co., Ltd.		421256261	manufacture(50814-016, 50814-011, 50814-013)

Revised: 3/2019 GFA Production (Xiamen) Co., Ltd.