

**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 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.

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:

REFILL
2

Made in China

REFILL INSTRUCTIONS

1. Remove old box from tabbed grid by slightly squeezing the front of box and pull straight out.
2. Insert the new product box into the grid with the removable panel facing the front, pushing it past the tabs, locking it into place.
3. Remove the upper half of the box front panel by hooking your finger into the hole, and pulling back. This will tear along the perforated edge and give access to the first aid product.



DayMark
Safety Systems

ANSI-ISEA Z308.1-2015

DayMark
Safety Systems

Antibiotic Application
Locion Antibiotica

10 packs IT113401

Drug Facts

Active ingredients (in each gram)	Purpose
Bacitracin zinc (bacitracin 400 units)	First aid antibiotic
Neomycin sulfate (neomycin 3.5 mg)	
Polymyxin B sulfate (polymyxin B 5,000 units)	

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

Warnings
For external use only.
Do not use in the eyes or over large areas of the body.
If you are allergic to any of the ingredients or longer than 1 week unless directed by a doctor.
Ask a doctor before use if you have:
animal bites or puncture wounds
animal bites or puncture wounds
animal bites or puncture wounds

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, petroleum, purified water



083491314405

Antiseptic Towelettes (50814-011-01) Labeling:

REFILL
2

Made in China

REFILL INSTRUCTIONS

1. Remove old box from tabbed grid by slightly squeezing the front of box and pull straight out.
2. Insert the new product box into the grid with the removable panel facing the front, pushing it past the tabs, locking it into place.
3. Remove the upper half of the box front panel by hooking your finger into the hole, and pulling back. This will tear along the perforated edge and give access to the first aid product.



DayMark
Safety Systems

ANSI-ISEA Z308.1-2015

Antiseptic Towelettes **DayMark** Toallitas Antisepticas
Safety Systems

10 wipes IT113408

DRUG FACTS - Antiseptic Towelette

Active Ingredient:	Purpose:
Benzalkonium Chloride 0.13 %	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.



083491314474

Refill 2 (50814-016-01) 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:50814-016
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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
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Route of Administration	TOPICAL
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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
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Route of Administration	TOPICAL
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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.