STANDARD ANSI FIRST AID- water, benzalkonium chloride, isopropyl alcohol, bacitracin zinc, neomycin sulfate, polymyxin b sulfate, lidocaine hydrochloride
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.

Standard ANSI First Aid Kit

Drug Facts

Active ingredient

Purified Water 99.1%

Purpose

Eyewash

Use

For cleansing the eye to help relieve irritation or burning by removing loose foreign material

Warnings

For external use only.

Do not use

if solution changes color or becomes cloudy

When using this product

• to avoid contamination, do not touch tip of container to any surface • do not reuse • once opened, discard • obtain immediate medical treatment for all open wounds in or near the eyes

Stop use and ask a doctor if

• you experience: • eye pain • changes in vision • continued redness • irritation of the eye • condition worsens or persists

Keep out of reach of children.

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

Directions

• Flush the affected eye as needed, controlling the rate of flow of solution by pressure on the bottle

Other information

• not for use as contact lens solution

• use before expiration date marked on the bottle

• store at room temperature, 5° to 35°C (41° to 95°F)

Inactive ingredients

Benzalkonium chloride, sodium chloride

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.

DRUG FACTS

Active Ingredient:

Isopropyl Alcohol, 70% v/v

Purpose:

Antiseptic

Use:

For preparation of the skin before injection.

Warnings:

For external use only.

Flammable - keep away from fire or flame.

Do not use:

with electrocautery, in the eyes

Stop use

if irritation and redness develop. If condition persists for more than 72 hours, consult your doctor.

Keep out of reach of children.

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

Directions:

Wipe injection site vigorously and discard.

Other information:

Store at room temperature 15°-30° C (59°-86° F)

Inactive ingredient:

Purified water.

Drug Facts

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

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 ingredients

Benzalkonium chloride 0.13%

Lidocaine hydrochloride 0.5%

Purpose

First aid antiseptic

Pain relieving cream

Uses

- First aid to help prevent infection in minor cuts, scrapes, and burns.
- For the temporary relief of pain and itching associated with minor burns , minor cuts, and scrapes

Warnings

For external use only.

Do not use

• in the eyes • over large areas of the body • in large quantities • over raw surfaces or blistered areas • 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 • symptoms persist for more than 7 days or clear up and occur

again within a few days

Keep out of reah of children.

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

Directions

- Clean the affected area
- Adults and children 2 years of age and older: Apply a small amount of this product to affected area not more than 3 times daily
- Children under 2 years of age: consult a doctor
- May be covered with a sterile bandage

Other information

Store at room temperature

Inactive ingredients

glycerin monostearate, glycerol, purified water

Drug Facts

Active ingredient

Ethyl alcohol 62%

Purpose

Antiseptic

Uses

- For handwashing to decrease bacteria on the skin
- Recommended for repeated use.

Warnings

Flammable, keep away from fire or flame

For external use only.

Do not use

in the eyes.

Stop use and ask a doctor if

- irritation and redness develop
- condition persists for more than 72 hours

Keep out of reach children.

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

Directions

- Wet hands thoroughly with product and allow to dry without wi

Other information

Store at 15° to 25°C (59° to 77°F)

Inactive ingredients

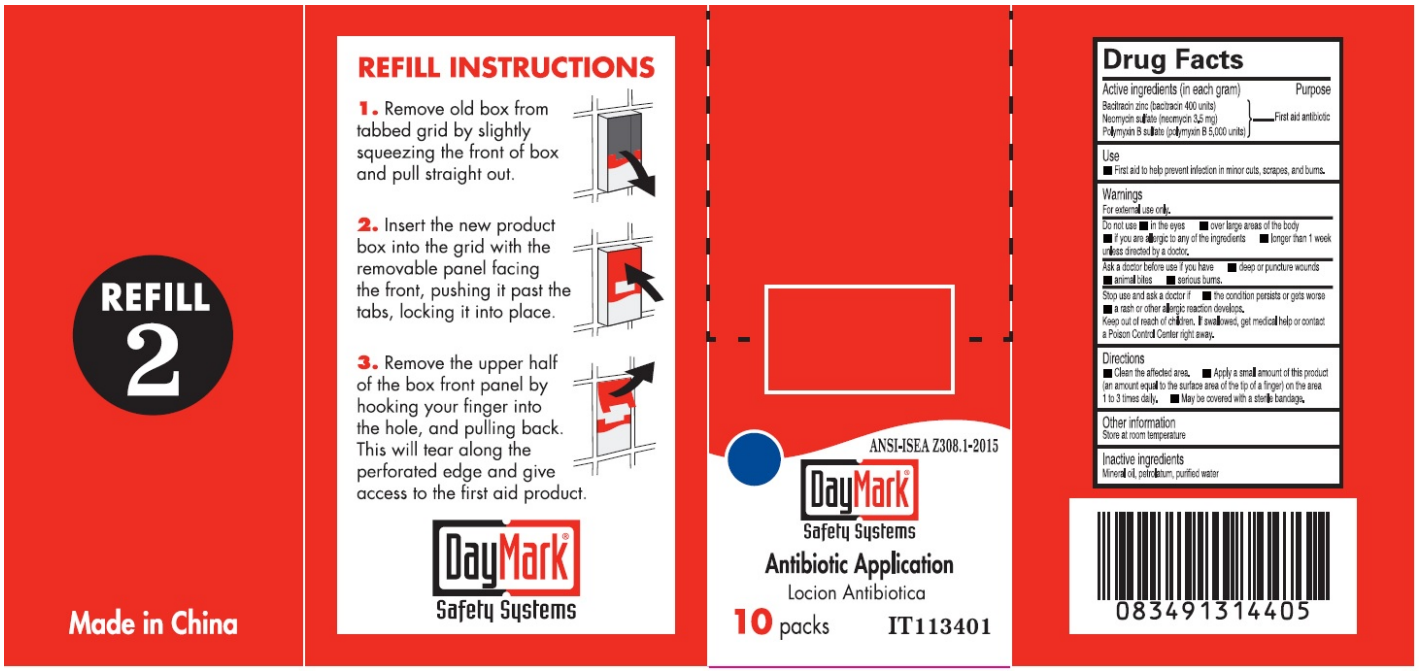
Carbomer, propylene glycol, purified water, titanium dioxide

Eye Wash (50814-010-01) Labeling:

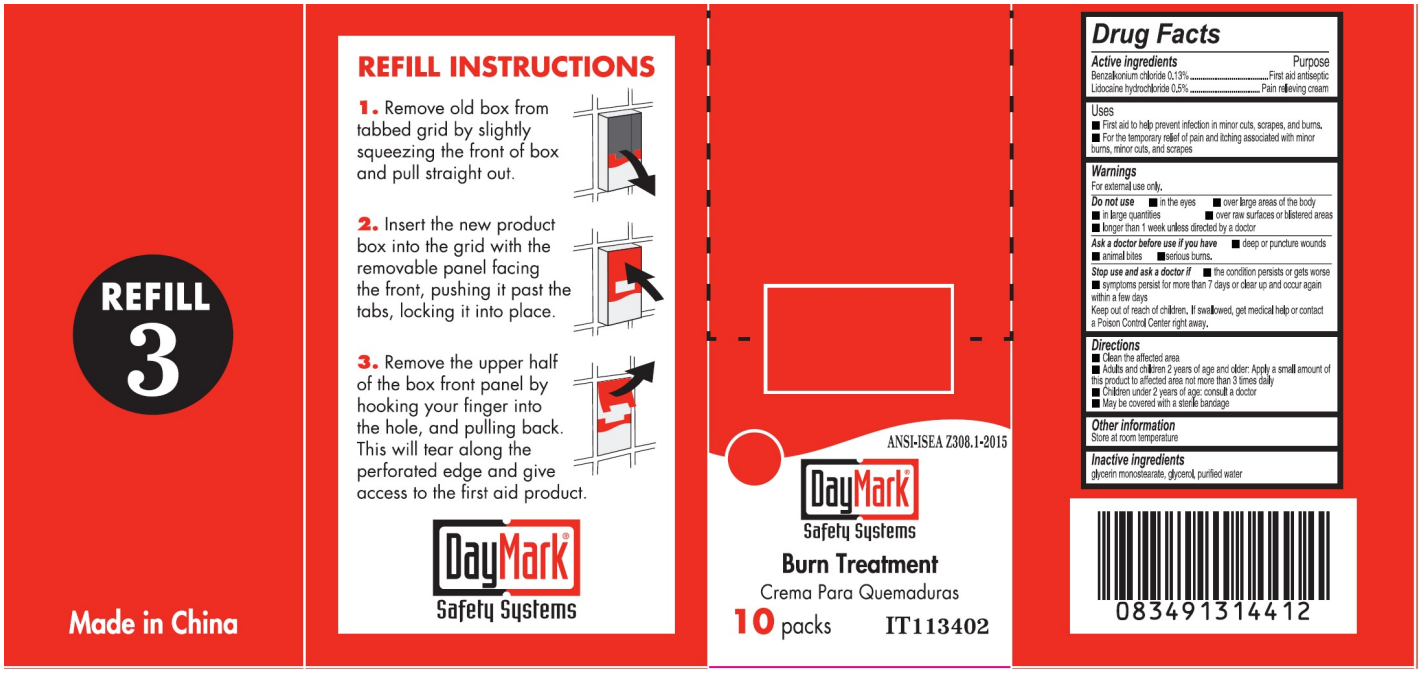
Antiseptic Towelettes (50814-011-01) Labeling:

Alcohol Cleansing Pads (50814-012-01) Labeling:

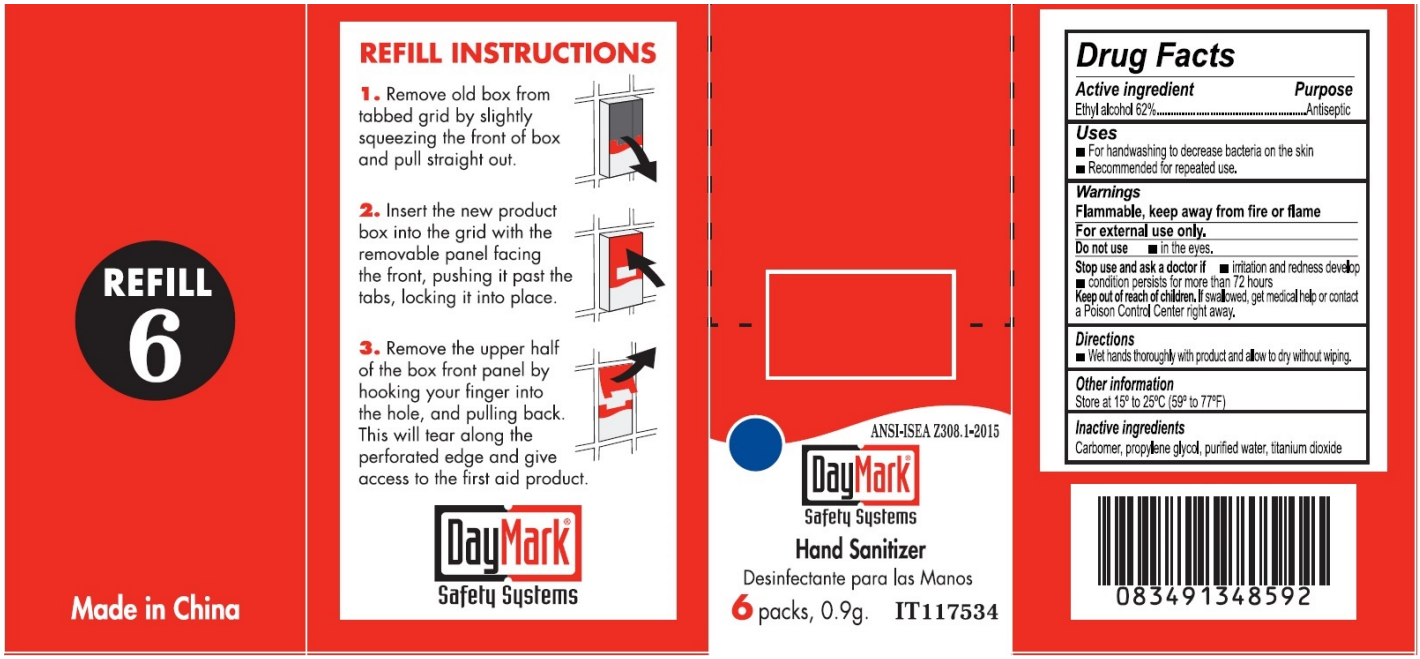
Antibiotic Application (50814-013-01) Labeling:



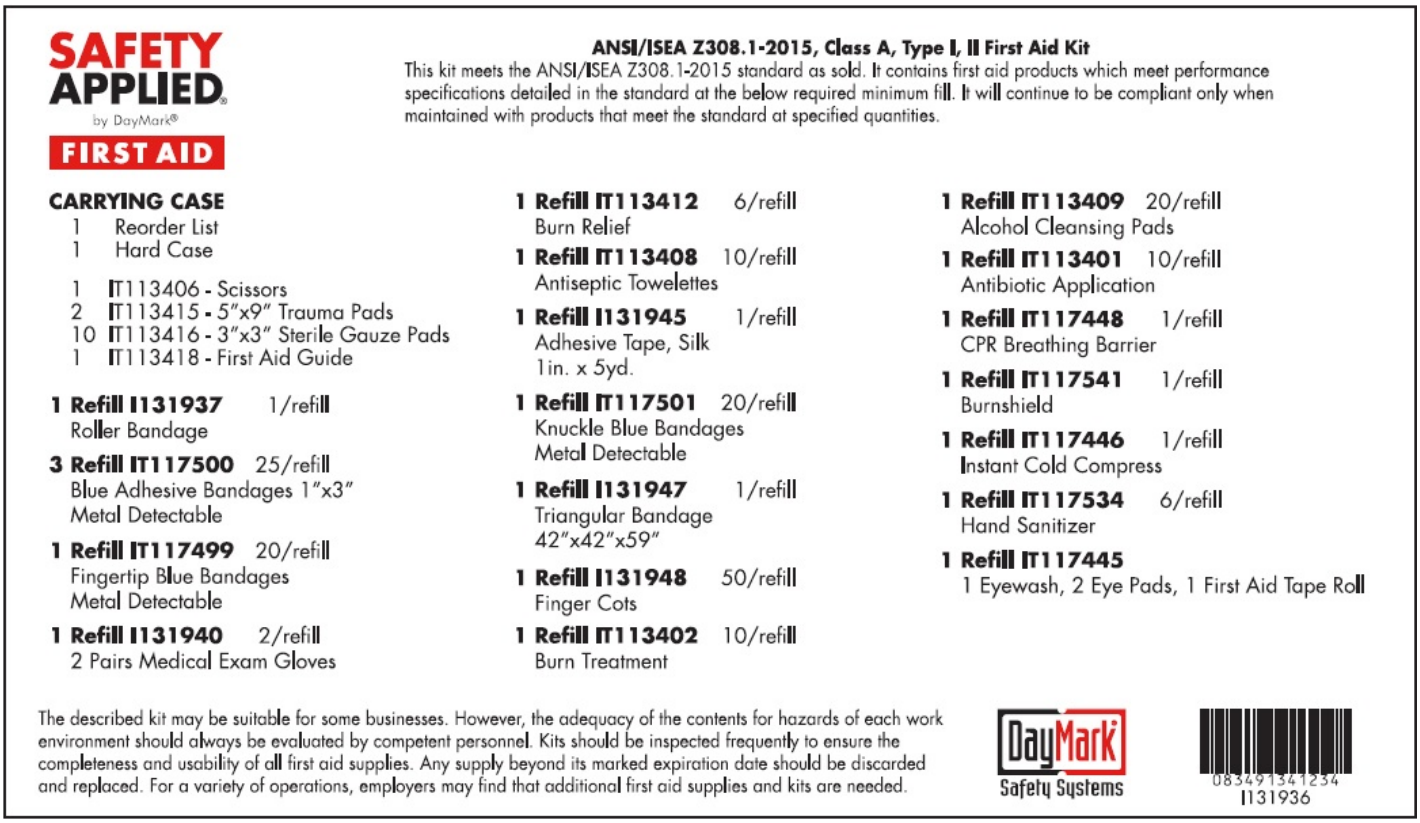
Burn Treatment (50814-014-01) Labeling:



Hand Sanitizer (50814-015-01) Labeling:



Standard ANSI First Aid (50814-020-01) Labeling:



STANDARD ANSI FIRST AID

water, benzalkonium chloride, isopropyl alcohol, bacitracin zinc, neomycin sulfate, polymyxin b sulfate, lidocaine hydrochloride kit

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50814-020

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50814-020-01	1 in 1 KIT	08/10/2016	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	30 mL
Part 2	10 PATCH	9 g
Part 3	10 PATCH	9 g
Part 4	6 PACKAGE	5 g
Part 5	10 PACKAGE	9 g
Part 6	6 PACKAGE	5.4 g

Part 1 of 6

EYE WASH

water solution

Product Information	
Item Code (Source)	NDC:50814-010
Route of Administration	OPHTHALMIC

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	991 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:50814-010-01	1 in 1 BOX		
1		30 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part349	08/10/2016	

Part 2 of 6

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	1 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 3 of 6

ALCOHOL CLEANSING

isopropyl alcohol cloth

Product Information	
Item Code (Source)	NDC:50814-012
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 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-	1 in 1 BOX		

1	012-01	1 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 4 of 6

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 PACKAGE; 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	

Part 5 of 6

BURN TREATMENT

benzalkonium chloride, lidocaine hydrochloride cream

Product Information	
Item Code (Source)	NDC:50814-014
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
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE	0.5 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:50814-014-01	1 in 1 BOX		
1		10 in 1 BOX		
1		0.9 g in 1 PACKAGE; 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 6 of 6

HAND SANITIZER

alcohol gel

Product Information

Item Code (Source)	NDC:50814-015
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.62 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50814-015-01	1 in 1 BOX		
1		6 in 1 BOX		
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 not final	part333A	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(50814-020, 50814-010, 50814-011, 50814-012, 50814-013, 50814-014, 50814-015)

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