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)

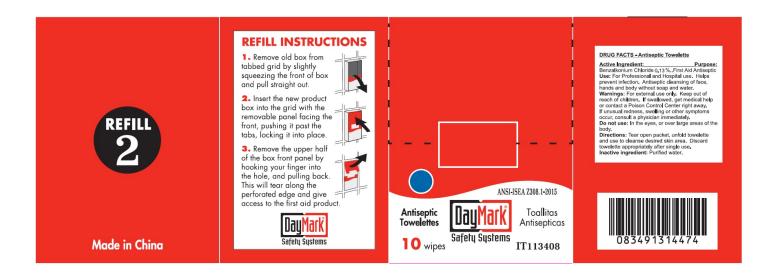
Inactive ingredients

Carbomer, propylene glycol, purified water, titanium dioxide

Eye Wash (50814-010-01) Labeling:



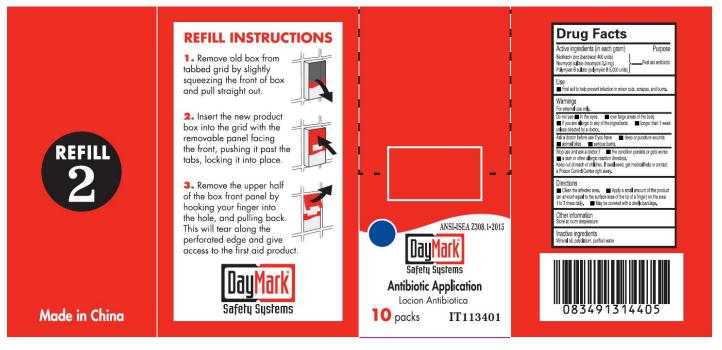
Antis eptic Towelettes (50814-011-01) Labeling:



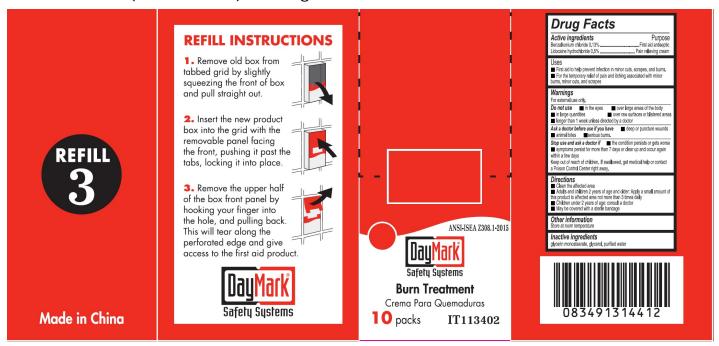
Alcohol Cleansing Pads (50814-012-01) Labeling:



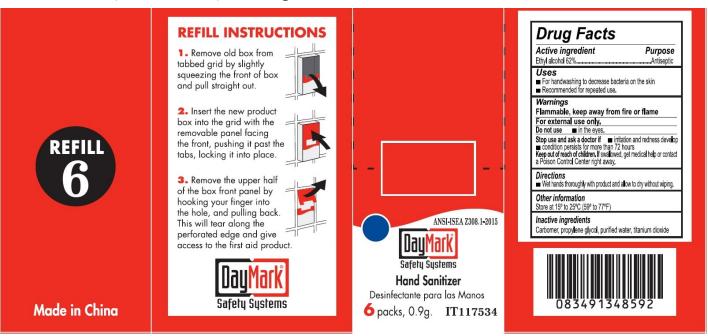
Antibiotic Application (50814-013-01) Labeling:



Burn Treatment (50814-014-01) Labeling:



Hand Sanitizer (50814-015-01) Labeling:



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



ANSI/ISEA Z308.1-2015, Class A, Type I, II First Aid Kit

This kit meets the ANSI/ISEA Z308.1-2015 standard as sold. It contains first aid products which meet performance specifications detailed in the standard at the below required minimum fill. It will continue to be compliant only when maintained with products that meet the standard at specified quantities.

CARRYING CASE

- Reorder List Hard Case
- T113406 Scissors

- 1 IT113418 First Aid Guide
- 1 Refill I131937 1/refill Roller Bandage
- 3 Refill IT117500 25/refill Blue Adhesive Bandages 1"x3" Metal Detectable
- Fingertip Blue Bandages Metal Detectable
- 1 Refill 1131940 2/refill 2 Pairs Medical Exam Gloves

- 1 Refill IT113412 6/refill Burn Relief
- 1 Refill IT113408 10/refill Antiseptic Towelettes
- 1 Refill | 1131945 1/refi Adhesive Tape, Silk 1in. x 5yd.
- 1 Refil [T117501 20/refi] Knuckle Blue Bandages Metal Detectable
- 1 Refill 1131947 1/refi Triangular Bandage 42"x42"x59"
- 1 Refill | 1131948 50/refi Finger Cots
- 1 Refill Π113402 10/refill **Burn Treatment**

- 1 Refill IT113409 20/refill Alcohol Cleansing Pads
- 1 Refill IT113401 10/refill Antibiotic Application
- 1 Refill IT117448 1/refill **CPR** Breathing Barrier
- 1 Refill | T117541 1/refi Burnshield
- 1 Refill IT117446 1/refill nstant Cold Compress
- 1 Refill IT117534 6/refill Hand Sanitizer
- 1 Refill | T117445 1 Eyewash, 2 Eye Pads, 1 First Aid Tape Roll

The described kit may be suitable for some businesses. However, the adequacy of the contents for hazards of each work environment should always be evaluated by competent personnel. Kits should be inspected frequently to ensure the completeness and usability of all first aid supplies. Any supply beyond its marked expiration date should be discarded and replaced. For a variety of operations, employers may find that additional first aid supplies and kits are needed.





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 End Date **Marketing Start Date** 1 NDC:50814-020-01 08/10/2016 1 in 1 KIT

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:50814-010Route of AdministrationOPHTHALMIC

Active Ingredient/Active Moiety

l	Ingredient Name	Basis of Strength	Strength
ı	WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	991 mg in 1 mL

Inactive Ingredients

inactive ingredients		
Ingredient Name	Strength	
BENZALKO NIUM CHLO RIDE (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
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g

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

F	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)	

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:50814-	1;n 1 DOV			

1	0 12-0 1	I III I DUA	
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: 89 Y4M234ES) (BACITRACIN - UNII:58 H6 RWO 52I)	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:J2VZ07J96K)	POLYMYXIN B	5000 [iU] in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
MINERAL O IL (UNII: T5L8T28FGP)		
PETROLATUM (UNII: 4T6 H12BN9 U)		
WATER (UNII: 059QF0KO0R)		

P	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 BENZALKO NIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM UNII:7N6 JUD5X6 Y) BENZALKONIUM CHLORIDE 0.13 g in 100 g LIDO CAINE HYDRO CHLORIDE (UNII: V13007Z41A) (LIDO CAINE - UNII:98 PI200987) LIDO CAINE HYDRO CHLORIDE 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: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	0.62 g in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
CARBO XYPO LYMETHYLENE (UNII: 0 A5MM307FC)		
PROPYLENE GLYCOL (UNII: 6 DC9 Q16 7 V3)		
WATER (UNII: 059QF0KO0R)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		

]	Packaging			
#	t 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)