FAK LARGE OFFICE FIRST AID KIT- benzalkonium chloride
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.

FAK Large Office First Aid kit

Antiseptic Towelettes - 113408 10 count (50814-011-01)
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.

Antiseptic Towelette (50814-002-01)
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.

Burn Treatment – 113402 10 count (50814-014-01)
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

Alcohol Cleansing Pads - 113409, 20 count (50814-012-01)
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.

Antibiotic Application - 113401 10 count (50814-013-01)
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

Hand Sanitizer – 117534 6 count (50814-015-01)
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

Eyewash - 117445 30ml (50814-010-01)
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

Eyewash 30ml (70897-002-03)
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

Package Labeling:

FIRST AID

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 INCLUDES:

- 1 Reorder List
- 1 Hard Case
- 1 IT113406 - Scissors
- 1 IT113407 - Tweezers
- 2 IT113415 - 5"x9" Trauma Pads
- 10 IT113416 - 3"x3" Sterile Gauze Pads
- 10 IT113417 - 2"x2" Sterile Gauze Pads
- 1 IT113418 - First Aid Guide
- 30 IT118413 - Blue Adhesive Bandages 1"x3" Metal Dectable
- 10 IT113408 - Antiseptic Towelettes
- 4 IT118429 - Eyewash 1oz

2 Boxes IT118413 30/box
Blue Adhesive Bandages 1"x3"
Metal Detectable

1 Box IT117499 20/box
Fingertip Blue Bandages
Metal Detectable

1 Box I131937 1/box
Roller Bandage

1 Box I131940 2/box
2 Pairs Medical Exam Gloves

1 Box IT113396 10/box
Moleskin (Blister Prevention)

2 Boxes IT113408 10/boxes
Antiseptic Towelettes

1 Box IT117501 20/box
Knuckle Blue Bandages
Metal Detectable

1 Box I131947 1/box
Triangular Bandage
42"x42"x59"

1 Box I131948 50/box
Finger Cots

1 Box IT113395 1/box
Elastic Bandage Wrap
with 2 fasteners

1 Box IT113412 6/box
Burn Relief

1 Box IT113402 10/box
Burn Treatment

1 Box IT113409 20/box
Alcohol Cleansing Pads

1 Box IT113401 10/box
Antibiotic Application

1 Box IT117448 1/box
CPR Breathing Barrier

1 Box IT117541 1/box
Burnshield

1 Box IT117446 1/box
Instant Cold Compress

1 Box IT117534 6/box
Hand Sanitizer

1 Box IT117445
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.

DayMark Safety Systems

083491353251
IT118411

C4RE™

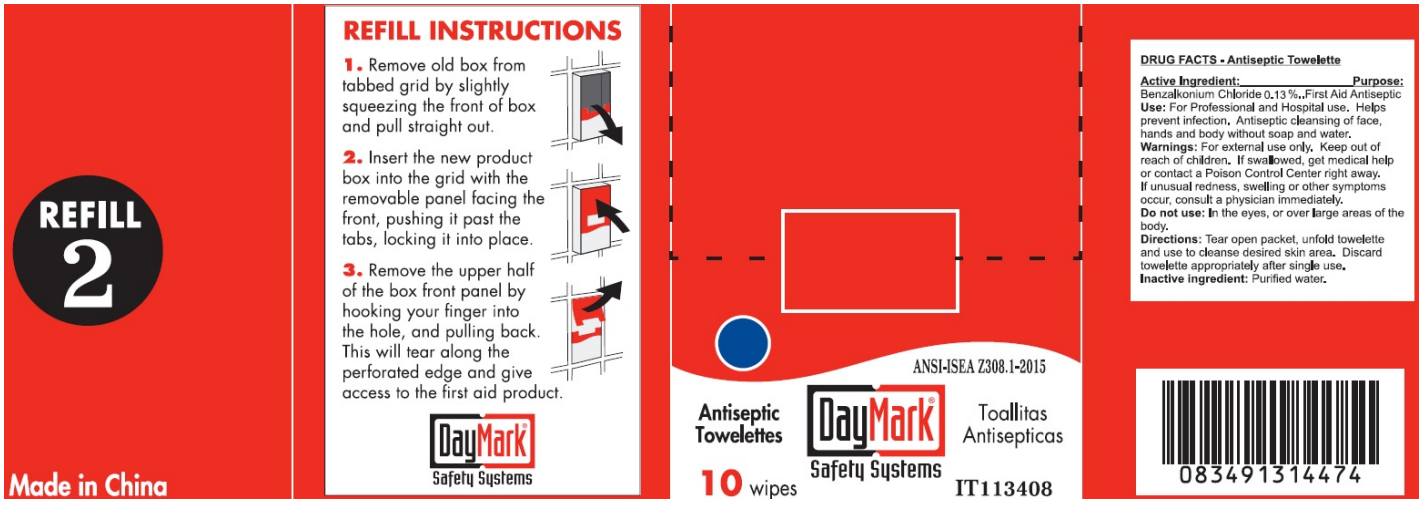
FIRST AID

by DayMark®

THIS KIT MEETS OSHA/ANSI REQUIREMENTS

CLASS A KIT

Antiseptic Towelettes



Antiseptic Towelette

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.

LOT/EXP:

TEAR HERE

REORDER AST-001

Antiseptic Towelette

Toallitas Antisepticas

CE 1 /pouch

GFA Production Xiamen Co., Ltd
www.gfaproduction.com

2

GFA Production Xiamen Co., Ltd
No. 20 Huli Industrial Park, Meixi Road,
Tong'an, Xiamen, Fujian, China 361100

EC REP Wellkang Ltd
Suite B, 29 Harley Street
LONDON W1G 9QR, England, United Kingdom

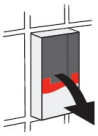
Burn Treatment

REFILL 3

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

Burn Treatment

Crema Para Quemaduras

10 packs IT113402

Drug Facts

Active ingredients	Purpose
Benzalkonium chloride 0,13%	First aid antiseptic
Lidocaine hydrochloride 0,5%	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 reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

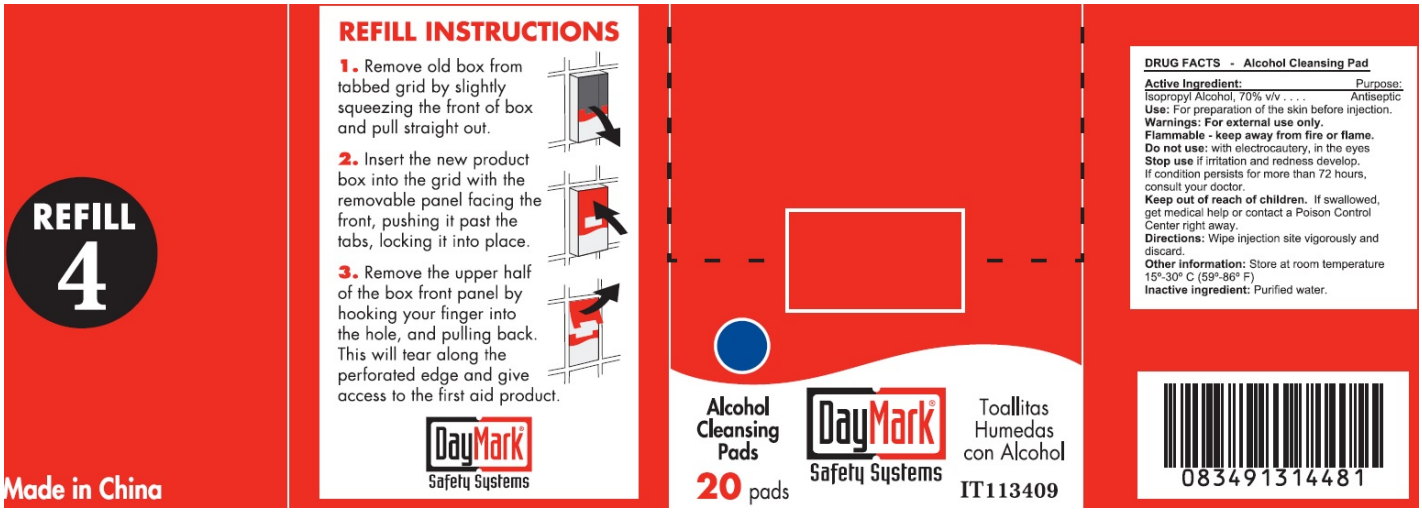
Directions
- Clean the affected area
- Adults and children 2 years of age and older: Apply a small amount of this product to affected area not more than 3 times daily
- Children under 2 years of age: consult a doctor
- May be covered with a sterile bandage

Other information
Store at room temperature

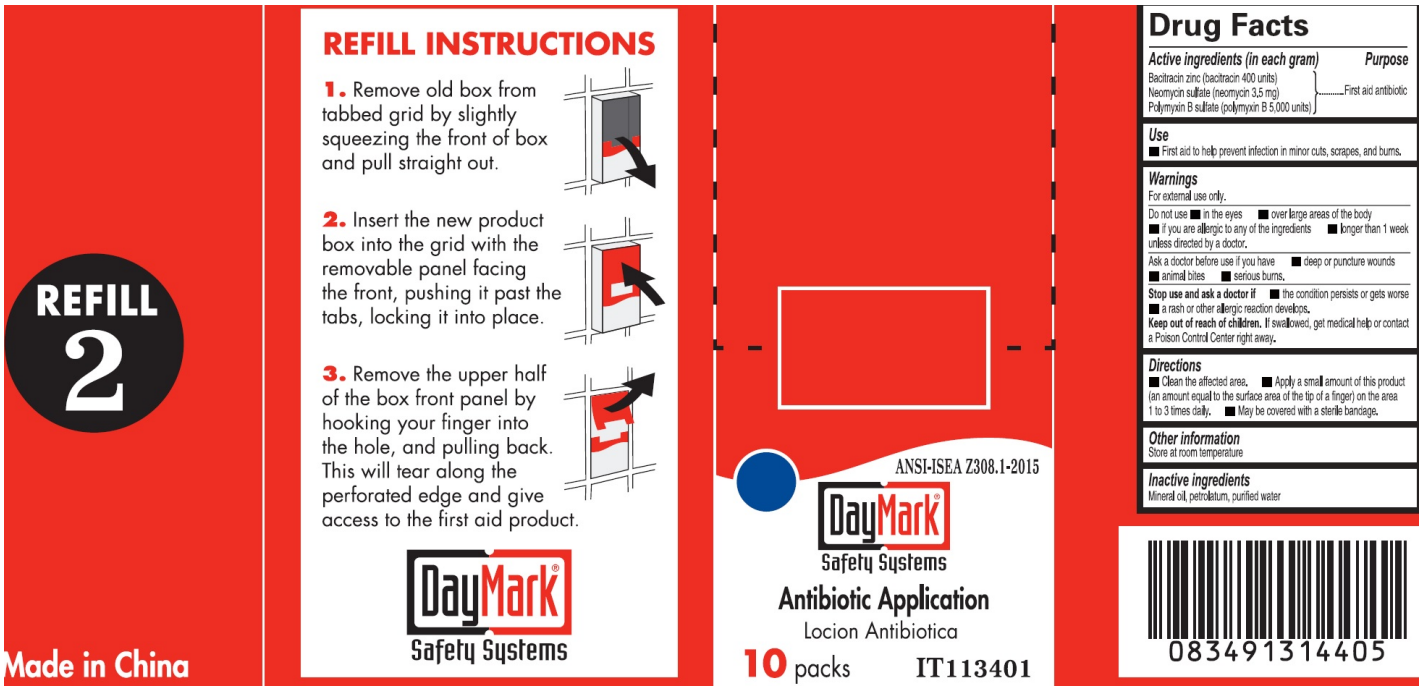
Inactive ingredients
glycerin monostearate, glycerol, purified water

083491314412

Alcohol Cleansing



Antibiotic Application



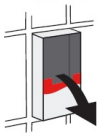
Hand Sanitizer

REFILL 6

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.

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ANSI-ISEA Z308.1-2015

DayMark Safety Systems

Hand Sanitizer

Desinfectante para las Manos

6 packs, 0.81mL IT117534

Drug Facts

Active ingredient **Purpose**

Ethyl alcohol 62%.....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 of 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 wiping.

Other information

Store at 15° to 25°C (59° to 77°F)

Inactive ingredients

Carbomer, propylene glycol, purified water, titanium dioxide

083491348592

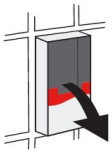
Eyewash

REFILL 6

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

Eye Wash, Eye Pads, First Aid Tape Roll 1/2" x 5yd.

Lavar Ojos, Almohadilla del Ojo, y Cinta

1 eye wash
2 eye pads
1 tape

IT117445

Drug Facts

Active ingredient **Purpose**

Purified Water 99.1% .....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

083491348134

Eyewash2

eyewash label
size: 33*70mm

Drug Facts

Active ingredient **Purpose**

Purified Water 99.1% ..... 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

EXPIRATION: 20190810 LOT: P010810

EYEWASH . DO NOT RE-USE. **DO NOT USE IF SEAL LOCATED AT CAP IS FOUND LEAKING. THIS UNIT NOT LABELED FOR RETAIL SALE. PLEASE RETAIN OUTER CONTAINER FOR COMPLETE DRUG FACTS INFORMATION.** FOR EXTERNAL USE ONLY. IF YOU EXPERIENCE EYE PAIN, CHANGES IN VISION,CONTINUED REDNESS OR IRRITATION OF THE EYE, OR IF THE CONDITION WORSENS OR PERSISTS, CONSULT A DOCTOR. OBTAIN IMMEDIATE MEDICAL TREATMENT FOR ALL OPEN WOUNDS IN OR NEAR THE EYES. IF SOLUTION CHANGES COLOR OR BECOMES CLOUDY, DO NOT USE. KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP ORCONTACT A POISON CONTROL CENTER RIGHT AWAY.
EXPIRATION: 20201221 LOT: P02L22

FAK LARGE OFFICE FIRST AID KIT

benzalkonium chloride kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50814-031

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:50814-031-01	1 in 1 KIT	02/08/2018	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 PATCH	1.8 g
Part 2	1 BAG	4.5 g
Part 3	1 PACKAGE	0.9 g
Part 4	1 PATCH	0.9 g
Part 5	1 PACKAGE	0.9 g
Part 6	1 PACKAGE	0.9 g
Part 7	1 TUBE	30 mL

Part 1 of 7

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	10 in 1 BOX		
1		1.8 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	02/08/2018	

Part 2 of 7

ANTISEPTIC TOWELETTE

benzalkonium chloride swab

Product Information

Item Code (Source)	NDC:50814-002
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:50814-002-01	1 in 1 BOX		
1		4.5 g in 1 BAG; 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	02/08/2018	

Part 3 of 7

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	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 not final	part333A	02/08/2018	

Part 4 of 7

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:50814-012-01	20 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	02/08/2018	

Part 5 of 7

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	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	02/08/2018	

Part 6 of 7

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	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	part333E	02/08/2018	

Part 7 of 7

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 final	part349	02/08/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349B	02/08/2018	

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

Establishment

Name	Address	ID/FEI	Business Operations
GFA Production (Xiamen) Co., Ltd.		421256261	manufacture(50814-031, 50814-011, 50814-002, 50814-014, 50814-012, 50814-013, 50814-015, 50814-010)

Revised: 10/2018 GFA Production (Xiamen) Co., Ltd.