4383 FIRST AID KIT- 4383 first aid
4384 FIRST AID KIT- 4384 first aid
Honeywell Safety Products USA, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

0498-4383, 4384: First Aid Kit (Triple, NaCl irr, EW, HC cr, BZK wipe, antiseptic hand gel, alcohol wipe- 148820, Z148820)

Triple
Active ingredient

Bacitracin zinc 400 units

Neomycin sulfate (5 mg equivalent to 3.5 mg Neomycin base)

Polymyxin B sulfate 5000 units

Triple
Purpose

First aid antibiotic

First aid antibiotic

First aid antibiotic

Triple
Uses

first aid to help prevent infection in:
- minor cuts
- scrapes
- burns

Triple
Warnings

For external use only

Allergy alert: **do not use if you are allergic to any of the ingredients**

Do not use
- in the eyes
- over large areas of the body
- Ask a doctor before use if you have

- a 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
- you need to use longer than 1 week

Keep out of the reach of children

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

Triple
Directions

- clean the affected area
- apply a small amount of the 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

Triple
Other information

- store at 15 ^{0} to 25 ^{0} C (59 ^{0} to 77 ^{0} F)
- tamper evident sealed packets
- do not use if packet is torn or opened

Triple
Inactive ingredient

petrolatum

Triple
Questions?

1-800-430-5490

BZK Wipe
Active ingredient

Benzalkonium chloride 0.13% w/v

BZK Wipe
Purpose

First aid antiseptic

BzK Wipe
Uses

Antiseptic cleansing of face, hands, and body without soap and water

BZK Wipe
Warnings

For external use only

Do not use
- in the eyes or over large areas of the body
- on mucous membranes
- on irritated skin
- in case of deep puncture wounds, animal bites or serious burns, consult a doctor
- longer than 1 week unless directed by a doctor

Stop use and ask a doctor if
- if irritation, redness or other symptoms develop
- the condition persists or gets worse

Keep out of reach of children

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

BZK Wipe
Directions

tear open packet and use as a washcloth

BZK Wipe
Other information

- store at room temperature 15 ^{0} to 30 ^{0} C (59 ^{0} - 86 ^{0} F)
- do not reuse towelette

BZK Wipe
Inactive ingredient

water

BZK Wipe
Questions

1-800-430-5490

Eyewash
Active ingredient

Sterile Water 99%

Eyewassh
Purpose

Eyewash

Eyewash
Uses

- for flushing the eye to remove loose foreign material, air pollutants or chlorinated water

Eyewash
Warnings

For external use only
- Obtain immediate medical treatment for all open wounds in or near eyes.
- To avoid contamination, do not touch tip of container to any surface.
- Do not reuse.
- Once opened, discard.

Do not use
- if solution changes color or becomes cloudy
- if you have open wounds in or near the eyes, get medical help right away.

Stop use and ask a doctor if
- you experience eye pain
- changes in vision
- continued redness or 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.

Eyeash
Directions
- remove contacts before using
- twist top to remove
- flush the affected area as needed
- control rate of flow by pressure on the bottle

- if necessary, continue flushing with emergency eyewash or shower

Eyewash
Inactive ingredients

sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic

Eyeash
Questions

Call 1-800-430-5490 Honeywell Safety Products USA, Inc. Smithfield, RI 02917

Hydrocortisone
Active ingredient (in each gram)

Hydrocortisone acetate (equivalent to Hydrocortisone 1%)

Hydrcortisone
Purpose

Anti-itch cream

Hydrocortisone
Uses

- for the temporary relief of itching associated with minor skin irritations and rashes

Hydrocortisone
Warnings

For external use only

Ask a doctor before use if
- you are using any other hydrocortisone product

When using the product

- avoid contact with eyes
- do not begin use of any other hydrocortisone product unless you have consulted a doctor
- do not use for the treatment of diaper rash

Stop use and ask a doctor if
- condition worsens
- condition persists for more than 7 days
- condition clears up and recurs within a few days

Keep out of reach of children

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

Hydrocortisone
Directions

- adults and children 2 years and older:
- clean the affected area
- apply to the area not more than 3 to 4 times daily
- children under 2 years of age: consult a doctor

Hydrocortisone
Other information

- store at room temperature (do not freeze)

Hydrocortisone
Inactive ingredients

cetyl alcohol, citric acid, diazolidinyl urea, edetate disodium, glycerin, glyceryl monostearate, methylparaben, mineral oil, polyethylene glycol, propylene glycol, propylparaben, purified water, stearic acid, trolamine

Hydrocortisone
Questions or Comments?

1-800-430-5490

Hand Sanitizer
Active ingredient

Ethyl alcohol 62%

Hand Sanitizer
Purpose

Antiseptic handwash

Hand Sanitizer
Uses

- for hand washing to decrease bacteria on skin
- recommended for repeated use

Hand Sanitizer

Warnings

For external use only

Flammable, keep away from fire or flame

When using this product

- do not use in the eyes
- discontinue use if irritation and redness develops. If condition persists for more than 72 hours consult a doctor.

Keep out of reach of children

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

Hand Sanitizer
Directions

wet hands thoroughly with product and allow to dry without wiping

Hand Sanitizer
Other information

- store at 15 ^{0} to 25 ^{0} C (59 ^{0} to 77 ^{0} F)

Hand Sanitizer
Inactive ingredients

acrylates/C10-30 alkyl acrylate crosspolymer, aloe barbadensis leaf juice, dl-alpha tocopheryl acetate, fragrance, PEG-60 almond glycerides, propylene glycol, purified water, triisopropanolamine

Hand Sanitizer
Questions or Comments?

1-800-275-3433 info@waterjel.com www.waterjel.com

Isotonic Solution for Irrigation.

For Irrigation Only.

Not for Injection.

Description
NaCL Irrigation

Each 100 mL contains:

Sodium Chloride USP 0.9 g; Water for Injection USP qs

pH adjusted with Hydrochloric Acid NF
pH: 5.0 (4.5–7.0) Calculated Osmolarity: 310 mOsmol/liter

Concentration of Electrolytes (mEq/liter): Sodium 154; Chloride 154
0.9% Sodium Chloride Irrigation USP is sterile, nonpyrogenic, isotonic and contains no bacteriostatic or antimicrobial agents.

The formula of the active ingredient is:
Ingredient Molecular Formula Molecular Weight
Sodium Chloride USP NaCl 58.44

The plastic container is a copolymer of ethylene and propylene formulated and developed for parenteral drugs. The copolymer contains no plasticizers and exhibits virtually no leachability. The plastic container is also virtually impermeable to vapor transmission and, therefore, requires no overwrap to maintain the proper drug concentration. The safety of the plastic container has been confirmed by biological evaluation procedures. The material passes Class VI testing as specified in the U.S. Pharmacopeia for Biological Tests — Plastic Containers. These tests have shown that the container is nontoxic and biologically inert.

The PIC™ Container is PVC-free and DEHP-free.

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The PIC™ Container is PVC-free and DEHP-free.

Clinical Pharmacology
NaCL Irrigant

0.9% Sodium Chloride Irrigation USP is utilized for a variety of clinical indications such as sterile irrigation of body cavities, tissues or wounds, indwelling urethral catheters, surgical drainage tubes, and for washing, rinsing or soaking surgical dressings, instruments and laboratory specimens. It also serves as a diluent or vehicle for drugs used for irrigation or other pharmaceutical preparations.

0.9% Sodium Chloride Irrigation USP provides an isotonic saline irrigation identical in composition with 0.9% Sodium Chloride Injection USP (normal saline).

Physiological irrigation solutions are considered generally compatible with living tissues and organs.

Sodium, the major cation of the extracellular fluid, functions primarily in the control of

water distribution, fluid balance, and osmotic pressure of body fluids. Sodium is also associated with chloride and bicarbonate in the regulation of the acid-base equilibrium of body fluid.

Chloride, the major extracellular anion, closely follows the metabolism of sodium, and changes in the acid-base balance of the body are reflected by changes in the chloride concentration.

Indication and Usage
NaCl Irrigant

0.9% Sodium Chloride Irrigation USP is indicated for all general irrigation, washing, rinsing and dilution purposes which permit use of a sterile, nonpyrogenic electrolyte solution.

Contraindications
NaCl Irrigant

0.9% Sodium Chloride Irrigation USP is not for injection by usual parenteral routes.

An electrolyte solution should not be used for irrigation during electrosurgical procedures.

Warnings
NaCl Irrigant

FOR IRRIGATION ONLY. NOT FOR INJECTION.

Irrigating fluids have been demonstrated to enter the systemic circulation in relatively large volumes; thus, irrigation solutions must be regarded as systemic drugs. Absorption of large amounts can cause fluid and/or solute overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema.

The risk of dilutional states is inversely proportional to the electrolyte concentrations of the administered parenteral solutions. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentration.

Do not warm above 150°F (66°C).

After opening container, its contents should be used promptly to minimize the possibility of bacterial growth or pyrogen formation.

Discard unused portion of irrigating solution since it contains no preservatives.

Precautions
NaCl Irrigant

General
Use aseptic technique when preparing and administering sterile irrigation solutions.

Use only if solution is clear and container and seal are intact.

Do not use for irrigation that may result in absorption of large amounts of fluid into the blood.

Caution should be observed when the solution is used for continuous irrigation or allowed to "dwell" inside body cavities because of possible absorption into the blood stream and the production of circulatory overload.

When used for irrigation via appropriate irrigation equipment, the administration set should be attached promptly. Unused portions should be discarded and a fresh container of appropriate size used for the start up of each cycle or repeat procedure. For repeated irrigations of urethral catheters, a separate container should be used for each patient.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid-base balance after prolonged irrigation, when fluid absorption is suspected, or whenever the condition of the patient warrants such evaluation.

Drug Interactions

Some additives may be incompatible. Consult with pharmacist.When introducing additives, use aseptic technique.Mix thoroughly.

Do not store.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies with 0.9% Sodium Chloride Irrigation USP have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy

Teratogenic Effects

Animal reproduction studies have not been conducted with 0.9% Sodium Chloride Irrigation USP. It is also not known whether 0.9% Sodium Chloride Irrigation USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. 0.9% Sodium Chloride Irrigation USP should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Safety and effectiveness of 0.9% Sodium Chloride Irrigation USP during labor and delivery have not been established. Caution should be exercised, and the fluid balance, glucose and electrolyte concentrations, and acid-base balance, of both mother and fetus should be evaluated periodically or whenever warranted by the condition of the patient or fetus.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when 0.9% Sodium Chloride Irrigation USP is administered to a nursing woman.

Pediatric Use

The safety and effectiveness of 0.9% Sodium Chloride Irrigation USP in pediatric patients have not been established. Its limited use in pediatric patients has been inadequate to fully define proper dosage and limitations for use.

Geriatric Use

Clinical studies of 0.9% Sodium Chloride Irrigation USP did not include a sufficient number of patients age 65 years and over to determine whether they respond differently from younger subjects. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function.Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.Frequent laboratory determinations and clinical evaluations are recommended to monitor changes in blood glucose, electrolyte concentrations, and renal function.

Adverse Reactions

Possible adverse effects arising from the irrigation of body cavities, tissues, or indwelling catheters and tubes can be minimized when proper procedures are followed. Displaced catheters or drainage tubes can lead to irrigation or infiltration of unintended structures or cavities. Excessive volume or pressure during irrigation of closed cavities may cause undue distension or disruption of tissues. Accidental contamination from careless technique may transmit infection.

If an adverse reaction does occur, discontinue administration of the irrigant, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

Overdosage

In the event of overhydration or solute overload, reevaluate the patient's condition, and institute appropriate corrective treatment. Intravasular volume overload may respond to hemodialysis. See WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.

Dosage and Administration

As required for irrigation.

When used as a diluent, or vehicle for other drugs, the drug manufacturer's recommendations should be followed.

Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Solutions should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permits.

How Supplied

0.9% Sodium Chloride Irrigation USP is supplied sterile and nonpyrogenic in PIC™ (Plastic Irrigation Container). The 1000 mL and 500 mL containers are packaged 16 per case, the 2000 mL containers are packaged 8 per case, and the 4000 mL containers are packaged 4 per case.

0.9% Sodium Chloride Irrigation USP

NDC Cat. No. REF SIZE

0264-2201-00 R5200-01 1000 mL
0264-2201-10 R5201-01 500 mL
0264-2201-50 R5205-01 2000 mL
0264-2201-70 R5207 ,,,,4000 mL

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protect from freezing. It is recommended that the product be stored at room temperature (25°C); however, brief exposure up to 40°C does not adversely affect the product.

Do not warm above 150°F (66°C).

SPL Unclassified Section

Rx only

Revised: March 2009

PIC is a trademark of B. Braun Medical Inc.

DIRECTIONS FOR USE OF PIC™ (PLASTIC IRRIGATION CONTAINER)

Not for injection.

Aseptic technique is required.

Caution – Before use, perform the following checks:

(a) Read the label. Ensure solution is the one ordered and is within the expiration date.

(b) Invert container and inspect the solution in good light for cloudiness, haze, or particulate matter; check the
container for leakage or damage. Any container which is suspect should not be used.

Use only if solution is clear and container and seal are intact

Single unit container. Discard unused portion.
Outer Closure Removal – Grasp the container with one hand and turn the breakaway ring counterclockwise with the other hand until slight resistance is felt. Then, twisting the container in the opposite direction, turn the breakaway ring sharply until the entire outer cap is loose and can be lifted off.

be lifted off.

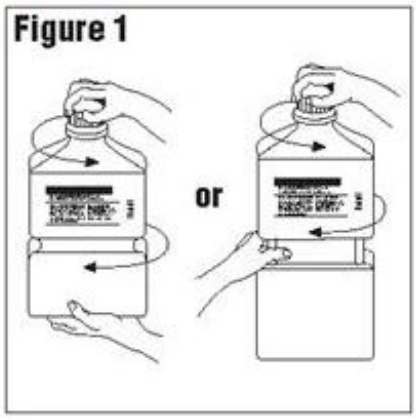

Figure 1

Connect the administration set through the sterile set port according to set instructions or remove screw cap and pour.

[Fig 2]

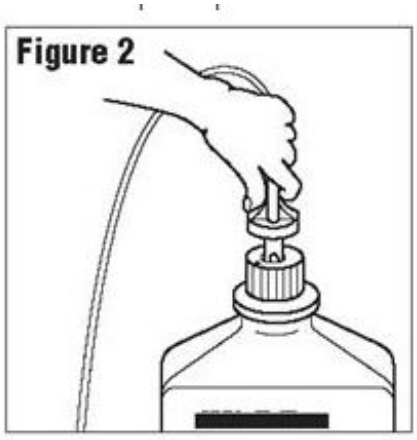

Figure 2

Do not warm above 150°F (66°C) to assure minimal bottle distortion. Keep bottles upright.

SPL Unclassified Section

B. Braun Medical Inc.
Irvine, CA 92614-5895 USA
Made in USA

Y36-002-699

Alcohol Wipe
Active ingredient

Isopropyl alcohol 70%

Alcohol Wipe
Purpose

First aid antiseptic

Alcohol Wipe
Uses

first aid to help prevent infection in minor cuts, scrapes, and burns

Alcohol Wipe
Warnings

For external use only

Flammable, keep away from fire and flame

Do not use
- in or near eyes
- over large areas of the body

Ask a doctor before use if you have
- deep or puncture wounds
- animal bites
- serious burns

When using this product

- do not use longer than 1 week unless directed by a doctor

Stop use and consult a doctor if

- condition persists or gets worse

Keep out of the reach of children

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

Alcohol Wipe
Directions
- clean the affected area
- may be covered with a sterile bandage
- apply wipe to affeted are 1 to 3 times daily

- discard wipe after single use

Alcohol Wipe
Other information

- store at room temperature 150 to 25 ^{0} C (59 ^{0} to 77 ^{0} oF)
- do not use if packet is torn or opened

Alcohol Wipe
Inactive ingredients

wateer

Alcohol Wipe
Questions

1-800-430-5490

4383
148820 Kit Contents

1 EYE DRESS PKT W/4 ADH STRIPS

1 ADHESIVE TAPE W/P 1" X 10YDS

1 ADH BDG, CLOTH, 1"X3", 16 PER

1 FIRST AID GUIDE ASHI

1 EMERGENCY SURVIVAL BLANKET

2 ELASTIC ROLLED GZ 3" ST

2 ELASTIC ROLLED GZ 4" ST

2 BLOODSTOPPER

8 ABD COMBINE PAD 5" X 9"

1 GZE PADS STERILE 3"X 3" 10'S

1 GZE PADS STERILE 4"X 4" 10'S

6 ABD PADS 8"X10" STERILE

4 MULTI-TRAUMA DRESSING 12"X30"

2 MEDI-RIP BANDAGE 6"X5YDS EA

4 ELASTIC BANDAGE 3" X 4.5YD

2 ELASTIC BANDAGE 6" X 4.5 YD

1 CPR FILTERSHIELD 77-100

1 FLASHLIGHT STD

1 RADIO AM FREQ BATTERY POWERED

1 WATER JEL FACIAL DRS 12X16 EA

1 TRIPLE BIOTIC .5 GRAM PKT 20

1 SOD. CHLORIDE 0.9% 500ML EA

1 4OZ BFS EYEWASH TRILINGUAL BOTTLE

1 SPHYG ANEROID(NO PIN) ADULT

1 STETHESCOPE NURSES VARIOUS COLORS

1 PENLIGHT DISPOSABLE EACH

1 FORCEPS WITH MAGNIFIER

1 SCISSOR UTILITY SHEARS 7-1/4"

1 SCISSOR LISTER BDG S/S 5 1/2"

1 BG POLY 32" x 34"

4 SPLINT BOARD W/PAD SML 12"X6"

1 LBL STOCK 6-3/8"X4"

1 LBL STOCK 4"X2-7/8"

1 LBL STOCK 3"x1-7/8"

1 10 PR NITRILE GLVES ZIP BAG

4 EMER.YELLOW BLKT 54"X80" POLYP

1 ANTISEPTIC HAND GEL 4OZ

1 ANTISEPTIC WIPES 20'S ZIP LOCK

1 HYDROCORTISONE 20'S ZIP LOCK

1 ALCOHOL WIPES 50'S ZIP LOCK

1 BAG FOR DELUXE TRAUMA KIT

4 COLD PACK 5"X 9" BULK

2 TRI BNDG NON WOVEN 40"X40"X56"

1 WOVEN KNUCKLE 8'S

1 FINGERTIP "T" 8/BX

4384
Z148820 Kit Contents

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1 ADH BDG, CLOTH, 1"X3", 16 PER

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1 SCISSOR LISTER BDG S/S 5 1/2"

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1 LBL STOCK 4"X2-7/8"

1 LBL STOCK 3"x1-7/8"

1 10 PR NITRILE GLVES ZIP BAG

4 EMER.YELLOW BLKT 54"X80" POLYP

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1 ANTISEPTIC WIPES 20'S ZIP LOCK

1 HYDROCORTISONE 20'S ZIP LOCK

1 ALCOHOL WIPES 50'S ZIP LOCK

1 BAG FOR DELUXE TRAUMA KIT

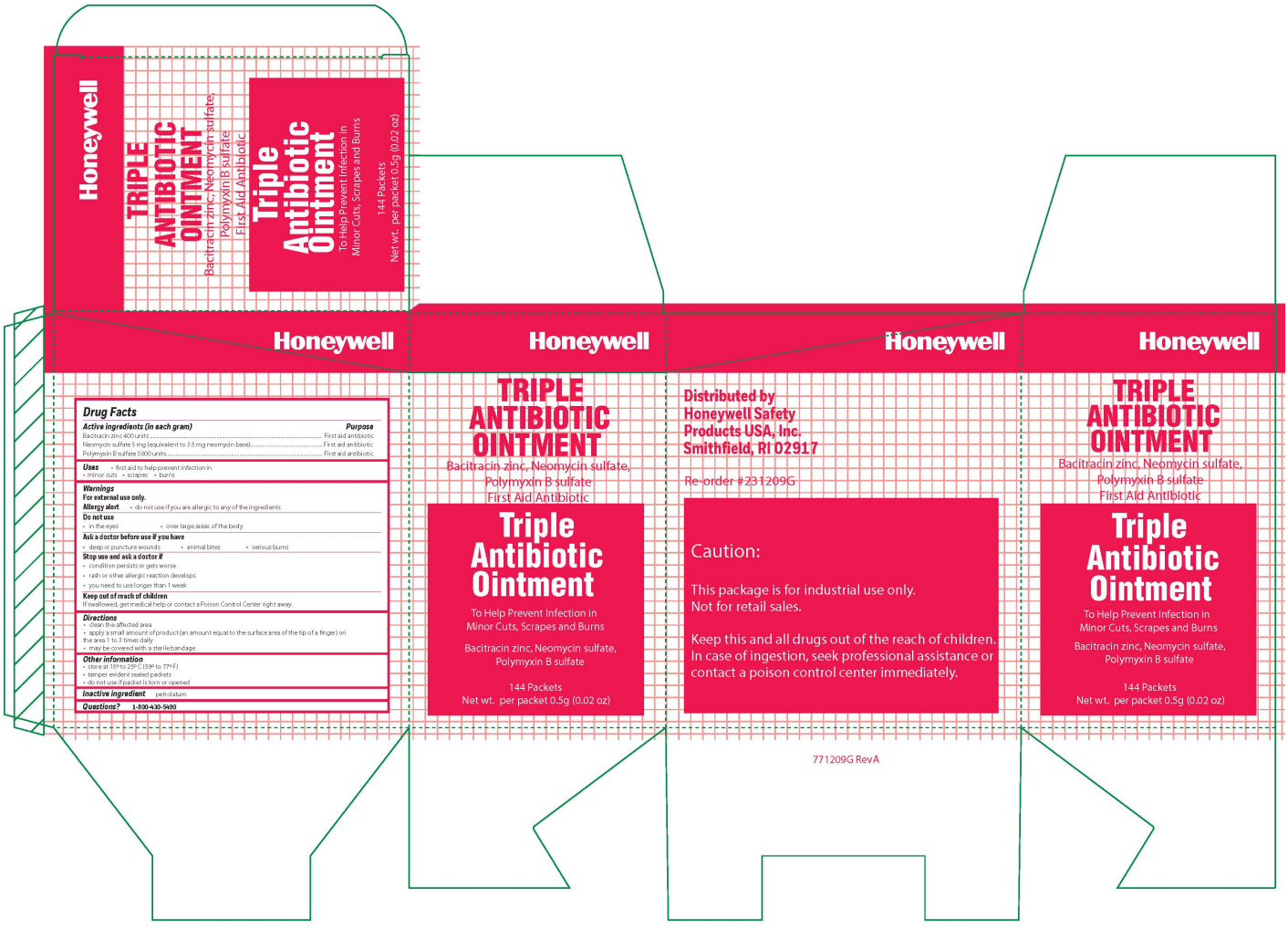
4 COLD PACK 5"X 9" BULK

2 TRI BNDG NON WOVEN 40"X40"X56"

1 WOVEN KNUCKLE 8'S

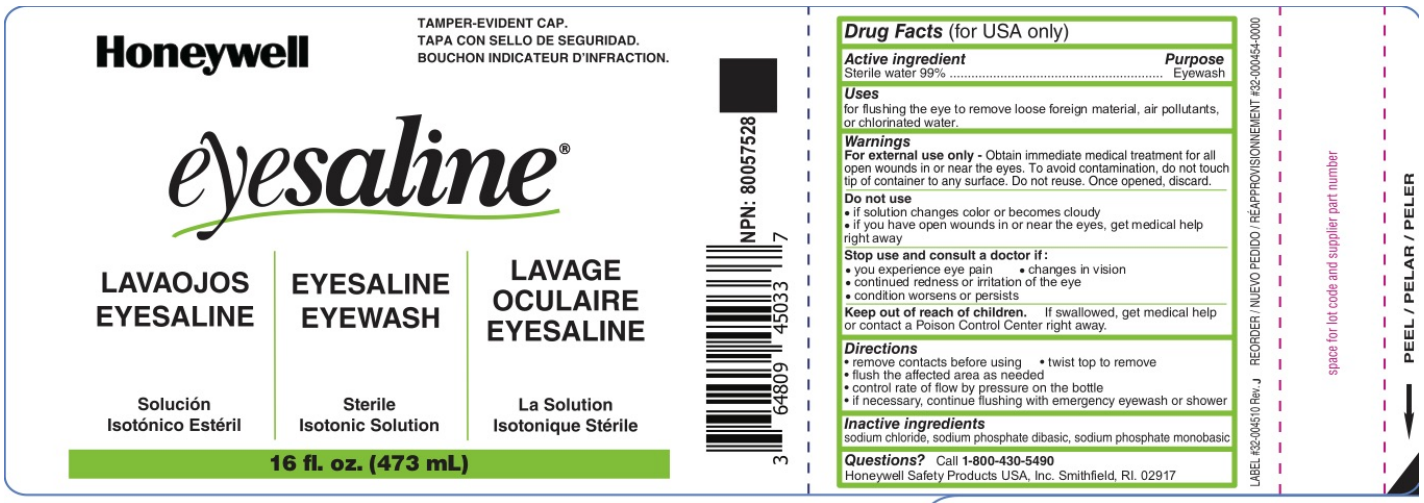
1 FINGERTIP "T" 8/BX

Triple
Principal Display Panel

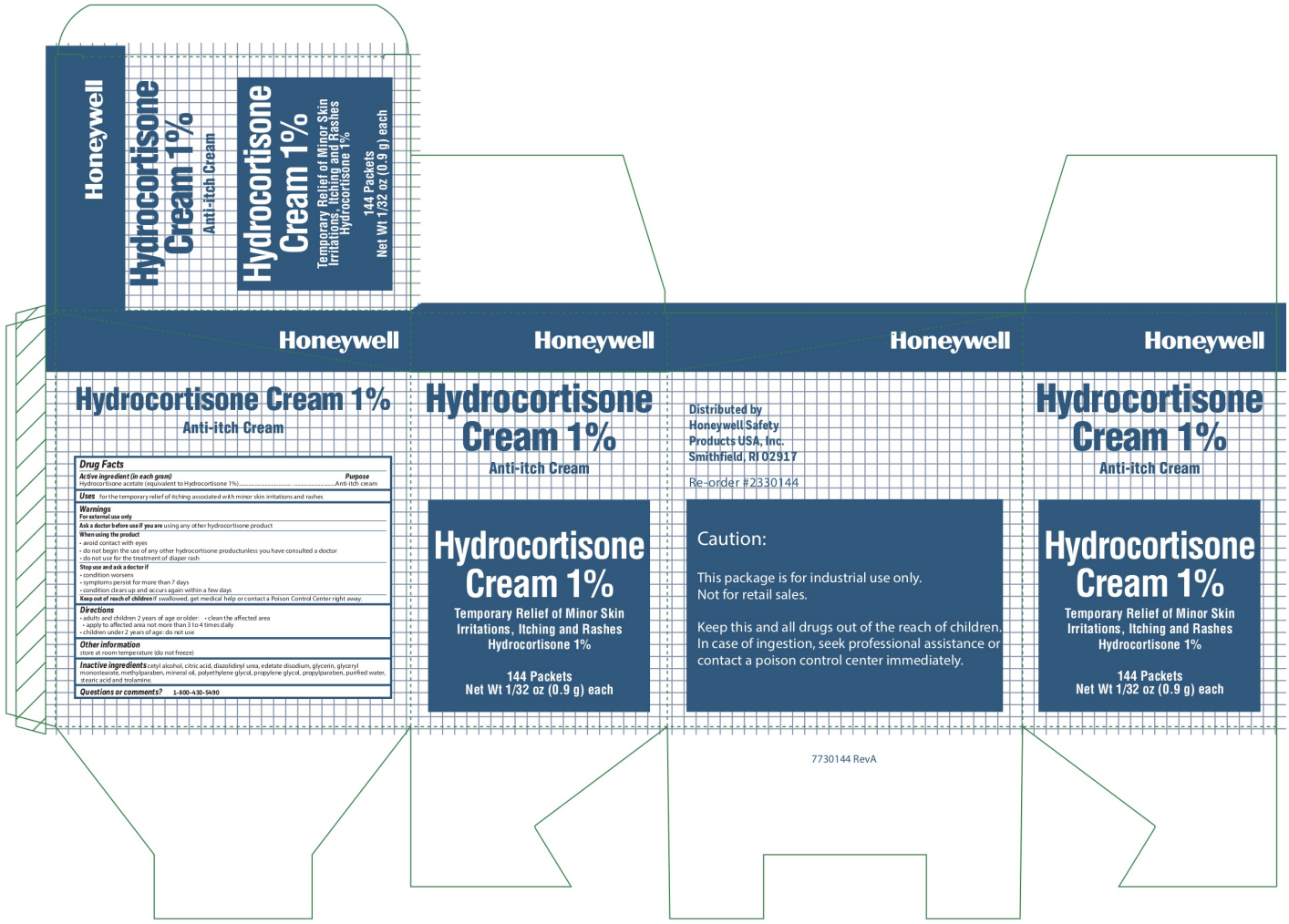


BZK Wipe
Principal Display Panel

Eyewash
Principal Display Panel



Hydrocortisone
Principal Display Panel



Hand Sanitizer
Principal Display Panel

INSTANT

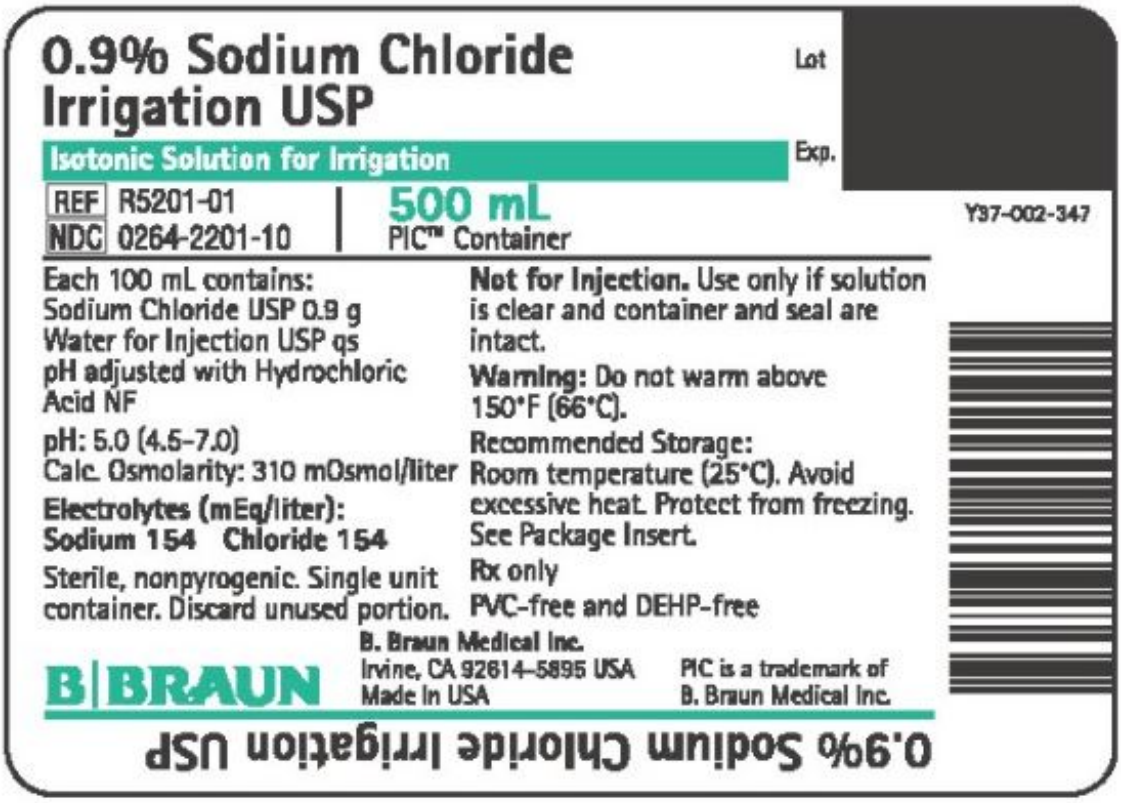
Hand Sanitizer

Antiseptic Gel
With Vitamin E & Aloe

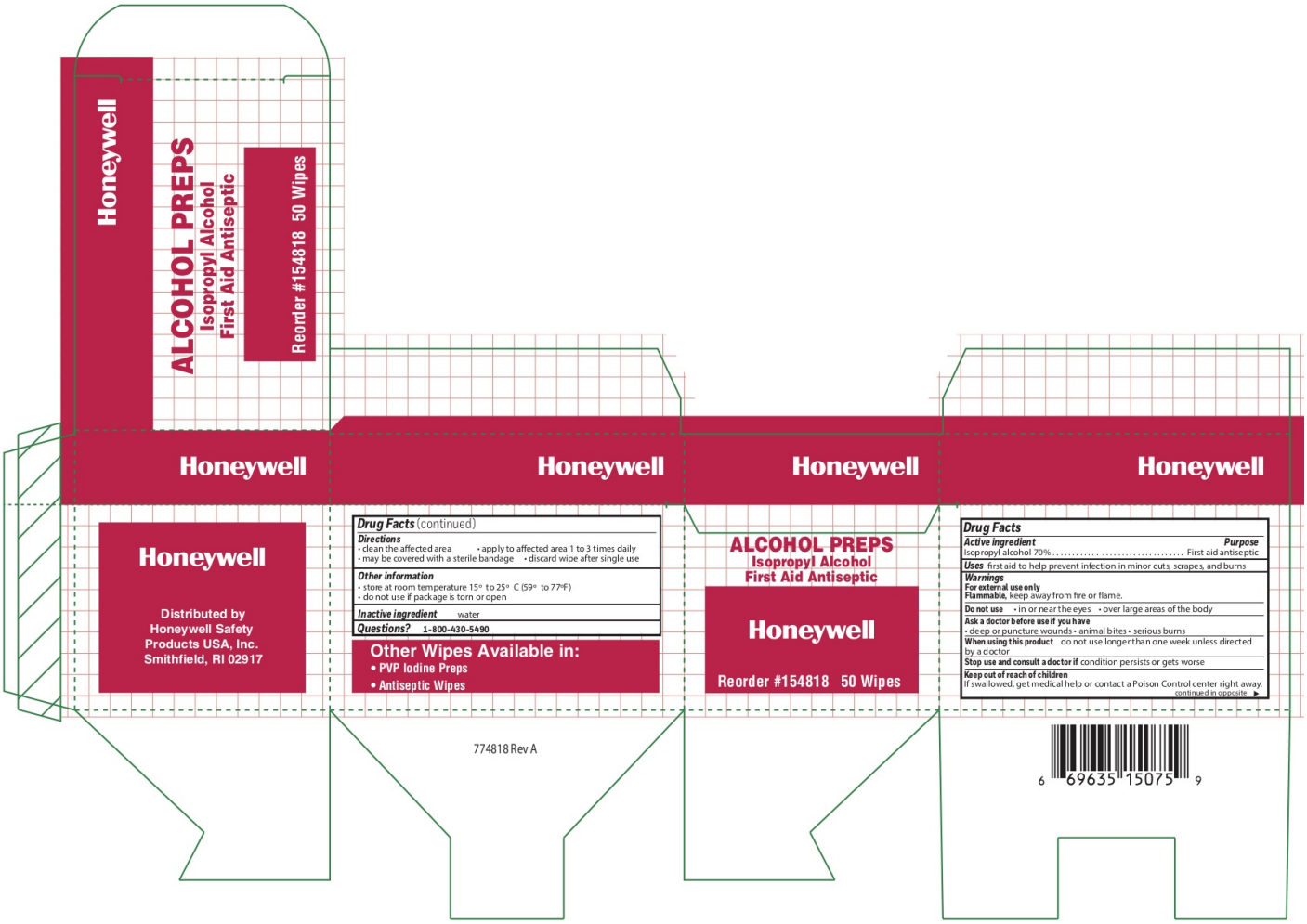
Kills 99.9% of Germs
Without Water

240mL - (8 fl oz)

Principal Display Panel 500 ml Container



Alcohol Wipe
Principal Display Panel



4383 Kit Label
148820

4384 Kit Label
Z148820

4383 FIRST AID KIT

4383 first aid kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0498-4383

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0498-4383-01	1 in 1 KIT	09/13/2018	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BOTTLE	118 mL
Part 2	20 PACKET	10 g
Part 3	20 PACKET	28 mL
Part 4	20 PACKET	18 g
Part 5	1 BOTTLE, PLASTIC	118 mL
Part 6	50 POUCH	20 mL
Part 7	1 CONTAINER	500 mL
Part 8	20 PACKET	18 g

Part 1 of 8

EYESALINE EMERGENCY EYEWASH

purified water liquid

Product Information	
Item Code (Source)	NDC:0498-0100
Route of Administration	OPHTHALMIC

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	98.6 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0498-0100-02	118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M018	12/18/2018	

Part 2 of 8

TRIPLE ANTIBIOTIC

bacitracin zinc, polymyxin b sulfate, neomycin sulfate ointment

Product Information	
Item Code (Source)	NDC:0498-0750
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	5000 [iU] in 1 g
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

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	

Product Characteristics

Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0750-36	0.5 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
unapproved drug other		09/19/2018	

Part 3 of 8

ANTISEPTIC TOWELETTE

benzalkonium chloride liquid

Product Information

Item Code (Source)	NDC:0498-0501
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM -	BENZALKONIUM	1.3 mg

UNII:7N6JUD5X6Y)	CHLORIDE	in 1 mL

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0498-0501-00	1.4 mL in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/22/2017	

Part 4 of 8

HYDROCORTISONE

anti-itch cream ointment

Product Information	
Item Code (Source)	NDC:0498-0800
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
TROLAMINE (UNII: 9O3K93S3TK)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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
unapproved drug other		03/06/2013	10/15/2019

Part 5 of 8

INSTANT HAND SANITIZER

alcohol liquid

Product Information

Item Code (Source)	NDC:59898-420
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
TRIISOPROPANOLAMINE (UNII: W9EN9DLM98)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59898-420-12	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/15/2010	

Part 6 of 8

ALCOHOL WIPE

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:0498-0143
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL

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

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0143-04	0.4 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/18/2018	

Part 7 of 8

SODIUM CHLORIDE

sodium chloride irrigant

Product Information	
Item Code (Source)	NDC:0264-2201
Route of Administration	IRRIGATION

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	0.9 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		500 mL in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/14/2009	

Part 8 of 8

HYDROCORTISONE

anti-itch cream

Product Information

Item Code (Source)	NDC:0498-0801
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
TROLAMINE (UNII: 9O3K93S3TK)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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
unapproved drug other		10/15/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

unapproved drug other		09/13/2018	

4384 FIRST AID KIT

4384 first aid kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0498-4384

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0498-4384-01	1 in 1 KIT	09/13/2018	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BOTTLE	118 mL
Part 2	20 PACKET	10 g
Part 3	20 PACKET	28 mL
Part 4	20 PACKET	18 g
Part 5	1 BOTTLE, PLASTIC	118 mL
Part 6	50 POUCH	20 mL
Part 7	1 CONTAINER	500 mL
Part 8	20 PACKET	18 g

Part 1 of 8

EYESALINE EMERGENCY EYEWASH

purified water liquid

Product Information	
Item Code (Source)	NDC:0498-0100
Route of Administration	OPHTHALMIC

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	98.6 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**

SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0100-02	118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M018	12/18/2018	

Part 2 of 8

TRIPLE ANTIBIOTIC

bacitracin zinc, polymyxin b sulfate, neomycin sulfate ointment

Product Information

Item Code (Source)	NDC:0498-0750
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	5000 [iU] in 1 g
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

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	

Product Characteristics

Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	

Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0750-36	0.5 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
unapproved drug other		09/19/2018	

Part 3 of 8

ANTISEPTIC TOWELETTE

benzalkonium chloride liquid

Product Information

Item Code (Source)	NDC:0498-0501
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0501-00	1.4 mL in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/22/2017	

Part 4 of 8

HYDROCORTISONE

anti-itch cream ointment

Product Information

Item Code (Source)	NDC:0498-0800
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
TROLAMINE (UNII: 9O3K93S3TK)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0800-34	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
unapproved drug other		03/06/2013	10/15/2019

Part 5 of 8

INSTANT HAND SANITIZER

alcohol liquid

Product Information

Item Code (Source)	NDC:59898-420
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
TRIISOPROPANOLAMINE (UNII: W9EN9DLM98)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59898-420-12	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/15/2010	

Part 6 of 8

ALCOHOL WIPE

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:0498-0143
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0498-0143-04	0.4 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
unapproved drug other		09/18/2018	

Part 7 of 8

SODIUM CHLORIDE

sodium chloride irrigant

Product Information	
Item Code (Source)	NDC:0264-2201
Route of Administration	IRRIGATION

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	0.9 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		500 mL in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/14/2009	

Part 8 of 8

HYDROCORTISONE

anti-itch cream

Product Information	
Item Code (Source)	NDC:0498-0801
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**

LIGHT MINERAL OIL (UNII: N6K5787QVP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
TROLAMINE (UNII: 9O3K93S3TK)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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
unapproved drug other		10/15/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/13/2018	

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