4385 FIRST AID KIT- 4385 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.

4385 First Aid Kit (PVP wipes, NaCl irr, EW, alcohol wipe, PAWS- 346100)

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

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 Vl 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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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.

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.

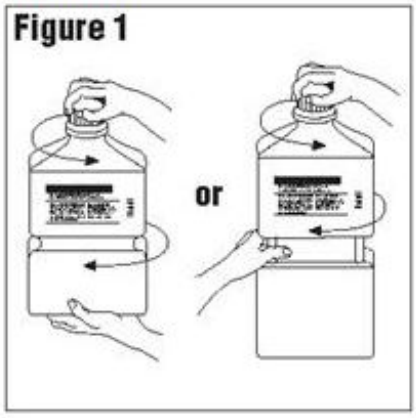


Figure 1

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

[Fig 2]

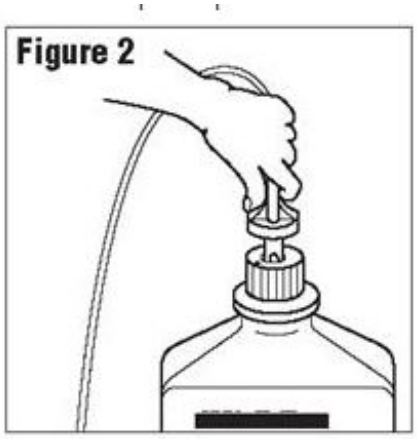


Figure 2

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 15 ^{o} to 25 ^{0} C (59 ^{0} to 77 ^{0} oF)
- do not use if packet is torn or opened

Alcohol Wipe
Inactive ingredients

water

Alcohol Wipe
Questions

1-800-430-5490

PVP Wipes
Active ingredients

Povidone-iodine 10%

(equivalent to 1% titratable iodine)

PVP Wipes
Purpose

First aid antiseptic

PVP Wipes
Uses
- first aid antiseptic to help prevent infection in minor cuts, scrapes and burns

PVP Wipes
Warnings

For external use only.

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

Stop use and ask a doctor if
- condition worsens or persists for more than 72 hours
- irritation and redness develops

Keep out of reach of children.

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

PVP Wipes
Directions
- clean the affected area
- apply1 to 3 times daily
- may be covered with a sterile bandage
- if bandaged, let dry first
- discard wipe after single use

PVP Wipes
Other Information
- do not use on individuals who are allergic or sensitive to iodine
- store at controlled temperature 59-86°F (15-30°C)
- do not use if pouch is open or torn

PVP Wipes
Inactive ingredients

nonoxynol 9, water

PVP Wipes
Questions

1-800-430-5490

PAWS
Active ingredient

Ethyl alcohol 66.5%

PAWS
Purpose

Antiseptic

PAWS
Uses

- for handwashing to decrease bacteria on skin whenever soap and water is not readily available

PAWS
Warnings

For external use only

Flammable: keep away from fire or flame

Do not use in the eyes.

If this happens, rinse thoroughly with water.

Stop use and ask a doctor if

- irritation or redness develop and 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

PAWS
Directions

- wet hands and wrists thoroughly for 15 seconds and allow to air dry
- always reseal after use
- children under 6 years of age should be supervised when using this product

PAWS
Inactive ingredients

aloe vera, fragrance, purified water, triethanolamine

PAWS
Questions

1-800-430-5490

4385
346100 Kit Contents

1 ALCOHOL PREP PADS 10P

1 PVP IODINE WIPES 10 PER

1 NITRILE GLOVES 2PR BBP

1 O/H TAPE ADHESIVE TRI-CUT

1 BK GZ 4.5"X4.1YD6PLY RL ST MSO

1 FIRST AID GUIDE ASHI

1 EMERGENCY SURVIVAL BLANKET

2 GAUZE CLEAN-WRAP BDGE N/S 2"

1 BLOODSTOPPER

2 ABD COMBINE PAD 5" X 9"

2 ABD PADS 8"X10" STERILE

1 SOD. CHLORIDE 0.9% 500ML EA

1 4OZ BFS EYEWASH TRILINGUAL BOTTLE

1 EMPTY BAG RED 8X8X6

1 LBL STOCK 6-3/8"X4"

1 LBL STOCK 4"X2-7/8"

1 LBL STOCK 3"x1-7/8"

1 POLY BAG, 19 X 24 (CLEAR)

1 BANDAGE PACK FOR KIT

1 ZIP LOCK BAG FOR KIT #3

1 SELF-ADH WRAP 3 X 5 YDS NORTH REV E

1 WATER-JEL BURN DRESSING 4 X 4

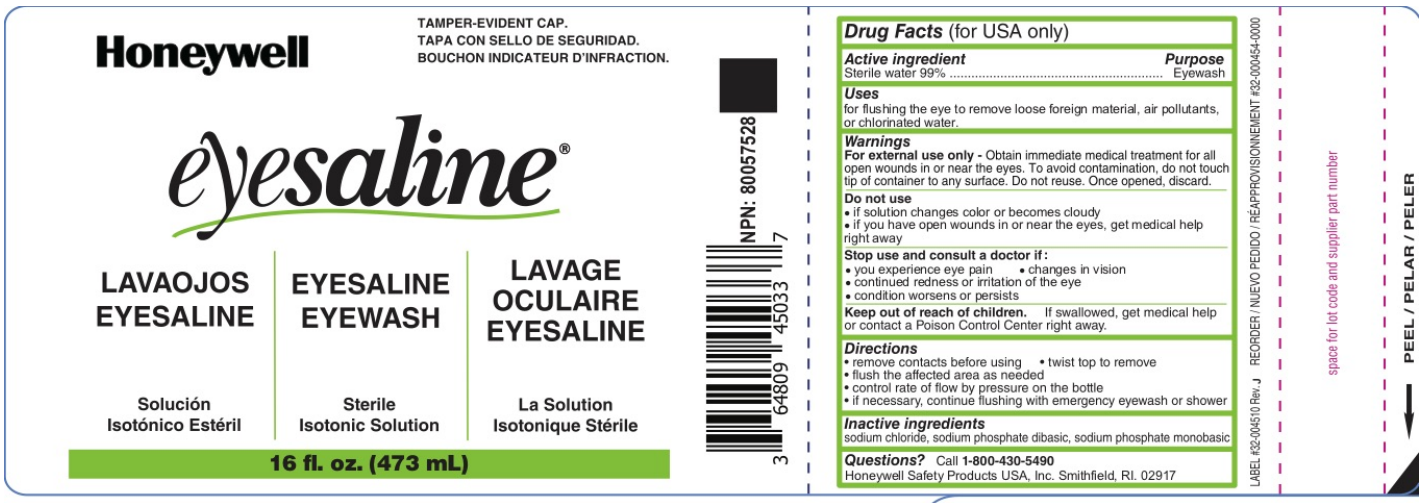
1 CORRUGATED 24PK 01-0810 RSC

1 TRI BNDG NON WOVEN 40"X40"X56"

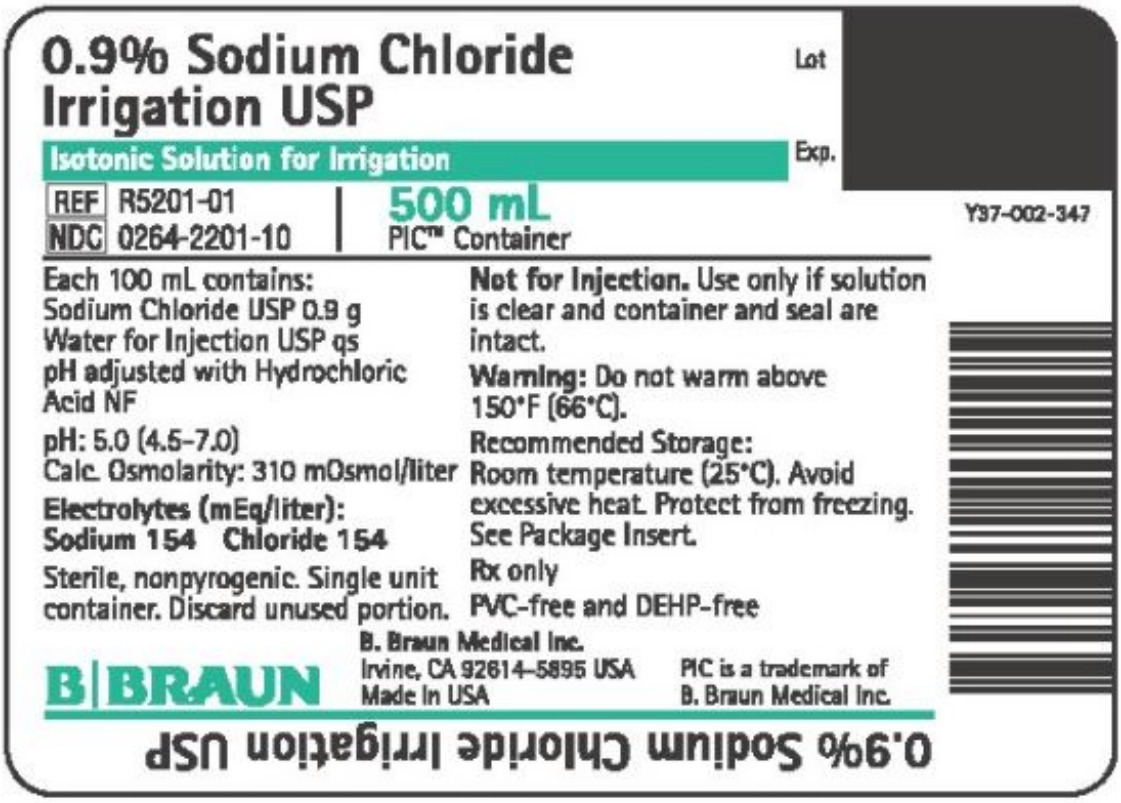
1 COLD PACK UNIT 4"X6" BULK

1 CPR MSK,PAWS WPS,GLVS 1

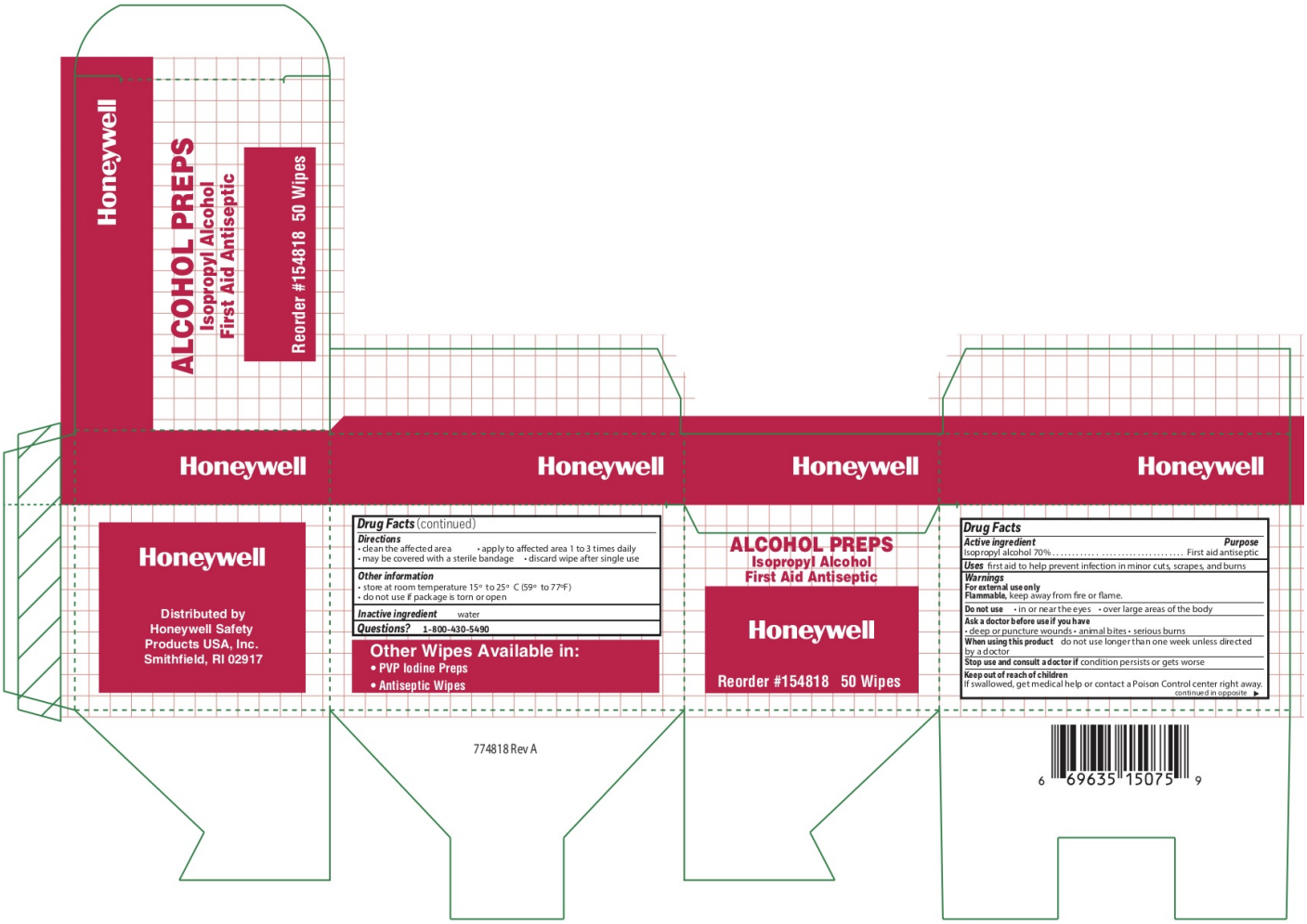
Eyewash
Principal Display Panel



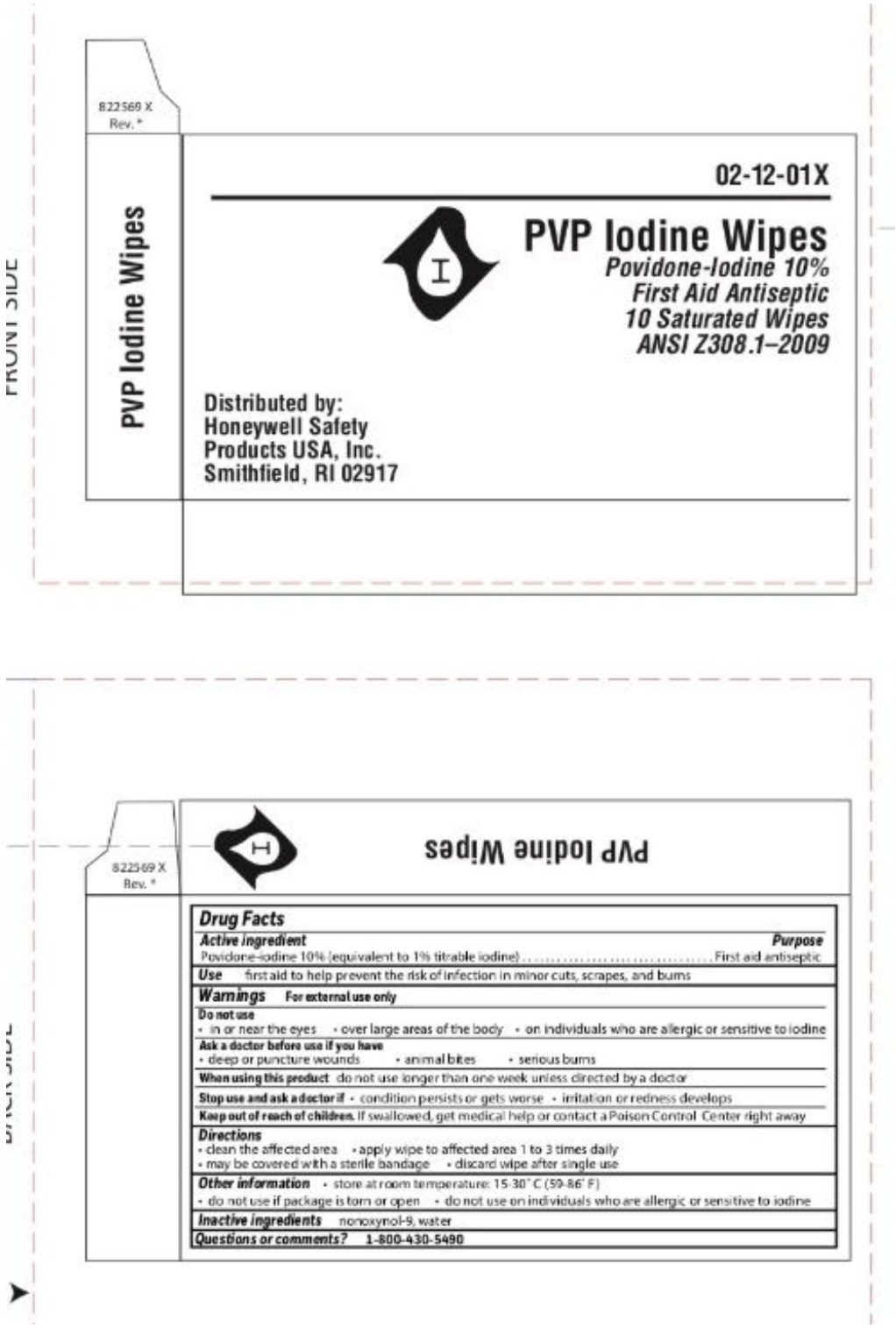
Principal Display Panel 500 ml Container



Alcohol Wipe
Principal Display Panel



PVP Wipes
Principal Display Panel



PAWS
Principal Display Panel

4385 Kit Label
346100

Distributed by Honeywell Safety Products USA, Inc. Smithfield, RI 02917

4385 FIRST AID KIT

4385 first aid kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0498-4385

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0498-4385-01	1 in 1 KIT	09/13/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 PACKET	0.0038 L
Part 2	10 POUCH	3 mL
Part 3	1 BOTTLE	118 mL
Part 4	10 POUCH	4 mL
Part 5	1 CONTAINER	500 mL

Part 1 of 5

PAWS

ethyl alcohol liquid

Product Information	
Item Code (Source)	NDC:0498-3111
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	665 mL in 1 L

Inactive Ingredients	
Ingredient Name	**Strength**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		0.0019 L in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	12/21/2017	

Part 2 of 5

PVP IODINE WIPE

povidone-iodine 10% swab

Product Information	
Item Code (Source)	NDC:0498-0121
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
NONOXYNOL-9 (UNII: 48Q180SH9T)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0498-0121-00	0.3 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 3 of 5

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 final	part349	12/18/2018	

Part 4 of 5

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
OTC monograph not final	part333A	09/18/2018	

Part 5 of 5

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
NDA	NDA016733	09/14/2009	

Marketing Information

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

Labeler - Honeywell Safety Products USA, Inc. (079287321)

Registrant - Honeywell Safety Products USA, Inc. (079287321)

Establishment

Name	Address	ID/FEI	Business Operations
B. Braun Medical Inc.		037425308	label(0264-2201)

Establishment

Name	Address	ID/FEI	Business Operations
Honeywell Safety Products USA, Inc		079287321	pack(0498-4385)

Establishment

Name	Address	ID/FEI	Business Operations
Honeywell Safety Products USA, Inc.		167518617	manufacture(0498-0100)

Establishment

Name	Address	ID/FEI	Business Operations
Changzhou Maokang Medical		421317073	manufacture(0498-0143)

Establishment

Name	Address	ID/FEI	Business Operations
Sion Medical Biotext		532775194	manufacture(0498-0121)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America Inc		874965262	manufacture(0498-3111)