

**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%

Eyewash

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 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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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. Intravascular 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 tilted on.

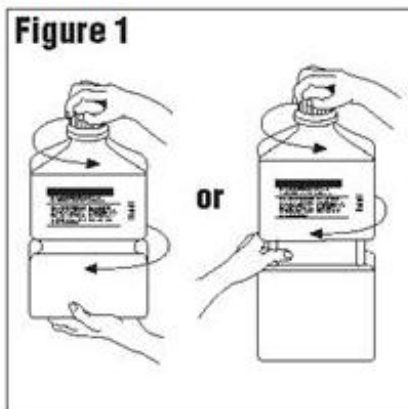


Figure 1

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

[Fig 2]

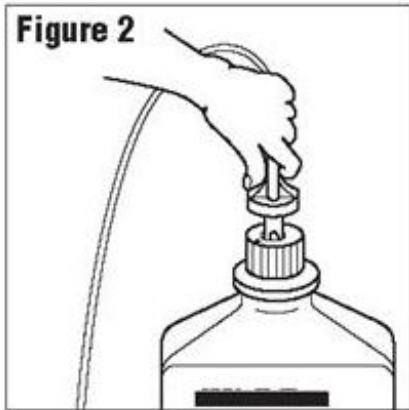


Figure 2

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 affected area 1 to 3 times daily
- discard wipe after single use

Alcohol Wipe***Other information***

- store at room temperature 15 ° to 25 ° C (59 ° to 77 ° 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
- apply 1 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

Honeywell

TAMPER-EVIDENT CAP.
TAPA CON SELLO DE SEGURIDAD.
BOUCHON INDICATEUR D'INFRACTION.

eyesaline®

LAVAOJOS
EYESALINE

Solución
Isotónico Estéril

EYESALINE
EYEWASH

Sterile
Isotonic Solution

LAVAGE
OCULAIRE
EYESALINE

La Solution
Isotonique Stérile

16 fl. oz. (473 mL)

NPN: 80057528
64809 1 45033 117

Drug Facts (for USA only)

Active ingredient Sterile water 99%
Purpose Eyewash
Uses for flushing the eye to remove loose foreign material, air pollutants, or chlorinated water.
Warnings For external use only - Obtain immediate medical treatment for all open wounds in or near the 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 consult 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.
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
Inactive ingredients sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic
Questions? Call 1-800-430-5490
Honeywell Safety Products USA, Inc. Smithfield, RI. 02917

LABEL #32-0045/0 Rev. J REORDER / NUEVO PEDIDO / REAPPROVISIONNEMENT #32-000454-0000

space for lot code and supplier part number

PEEL / PELAR / PELEL

Datos de medicamento (Para EE.UU. solamente)

Ingrediente Activo Agua estéril 99%
Propósito Lavaojos
Usos para el lavado de ojo para quitar las partículas sueltas y extrañas, los contaminantes aeros, o agua de cloruro
Advertencias
Para el uso externo sólo - Obtenga tratamiento médico inmediato para todas las heridas abiertas en o cerca de los ojos. Para evitar la contaminación, no toque la punta del envase con ninguna superficie. No vuelva a usar. Vez abierto, descarte.
No se use • si la solución se enturbia o cambia de color
• si tiene heridas abiertas en o cerca del ojo, obtenga ayuda medica de inmediato
Deje de usar y consulte a un médico si:
• experimenta dolor de ojo • cambio de visión
• rojez continuo o irritación del ojo
• la condición empeora o persiste
Manténgase fuera del alcance de los niños.
En caso de ingestión accidental, obtenga atención médica o llame a un Centro de control de envenenamiento inmediatamente.
Instrucciones
• quite los lentes de contacto antes de usar la solución
• tuerza la tapa para quitar
• enjuague el área afectada según se necesite
• controle el chorro haciendo presión el la botella
• si es necesario, sigue enjuagado con un lavaojos o ducha de emergencia
Ingredientes inactivos cloruro de sodio, fosfato de sodio dibásico, fosfato de sodio monobásico
¿Preguntas? Llame al 1-800-430-5490
Honeywell Safety Products USA, Inc. Smithfield, RI. 02917

Information

Usages Pour le rinçage des yeux afin d'enlever un corps étranger, des polluants atmosphériques ou de l'eau chlorée.
Advertissements
Pour usage externe seulement - Obtenir immédiatement des soins médicaux pour toutes les plaies ouvertes dans ou près des yeux. Pour éviter toute contamination, ne pas toucher la pointe du récipient à n'importe quelle surface. Ne pas réutiliser. Une fois ouvert, jeter.
Ne pas utiliser
• si la solution a changé de couleur ou si elle est brouillée
• si vous avez des plaies ouvertes aux yeux ou à proximité, consultez immédiatement un médecin
Cesser d'utiliser la solution et consulter un médecin
• vous ressentez une douleur oculaire • si votre vision change
• rougeur ou irritation persistante des yeux
• condition empire ou persiste
Garder hors de la portée des enfants.
En cas d'ingestion, communiquer immédiatement avec un médecin ou avec un centre antipoison.
Mode d'emploi
• enlever les verres de contact avant l'utilisation • dévisser le bouchon pour l'enlever • rincer la zone touchée selon les besoins • ajuster le débit d'écoulement de la solution en augmentant ou en réduisant la pression exercée sur le contenant
• si nécessaire, continuer de rincer avec une solution de rinçage oculaire d'urgence ou une douche
Ingédients eau stérile, chlorure de sodium, phosphate dibasique de sodium, phosphate monobasique de sodium
Des questions? Faites le 1-800-430-5490
Honeywell Safety Products USA, Inc. Smithfield, RI. 02917

Principal Display Panel 500 ml Container

0.9% Sodium Chloride Irrigation USP

Lot

Isotonic Solution for Irrigation

Exp.

REF R5201-01
NDC 0264-2201-10

500 mL
PIC™ Container

Y37-002-347

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)
Calc. Osmolarity: 310 mOsmol/liter
Electrolytes (mEq/liter):
Sodium 154 Chloride 154
Sterile, nonpyrogenic. Single unit container. Discard unused portion.

Not for Injection. Use only if solution is clear and container and seal are intact.

Warning: Do not warm above 150°F (66°C).

Recommended Storage: Room temperature (25°C). Avoid excessive heat. Protect from freezing. See Package Insert.

Rx only
PVC-free and DEHP-free

B|BRAUN

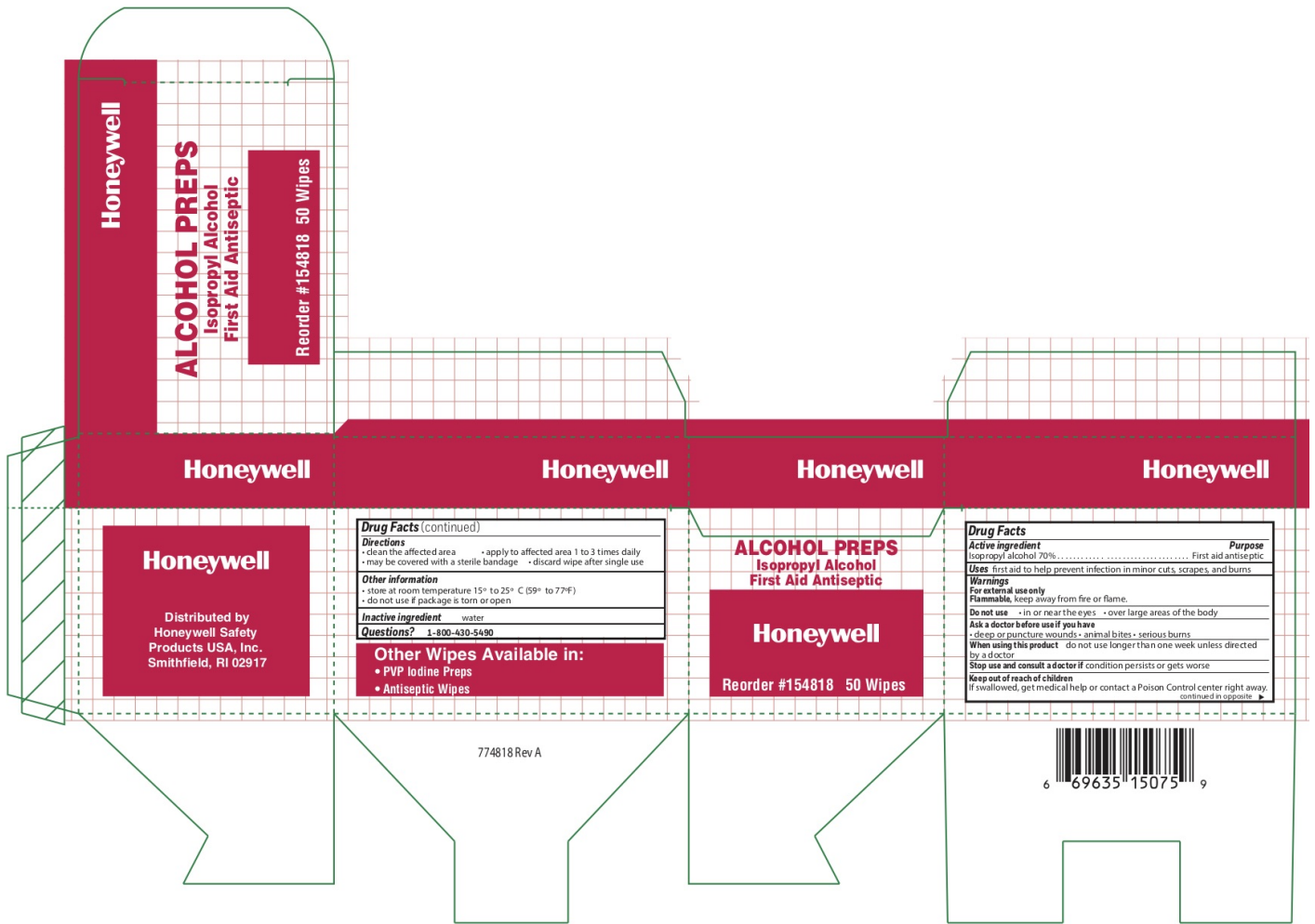
B. Braun Medical Inc.
Irvine, CA 92614-5895 USA
Made in USA

PIC is a trademark of
B. Braun Medical Inc.

0.9% Sodium Chloride Irrigation USP



Alcohol Wipe
Principal Display Panel



PVP Wipes
Principal Display Panel

FRONT SIDE

822569 X
Rev. *

PVP Iodine Wipes

02-12-01X



PVP Iodine Wipes
Povidone-Iodine 10%
First Aid Antiseptic
10 Saturated Wipes
ANSI Z308.1-2009

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

BACK SIDE

822569 X
Rev. *



PVP Iodine Wipes

Drug Facts

Active ingredient Povidone-iodine 10% (equivalent to 1% titrable iodine) **Purpose** First aid antiseptic

Use first aid to help prevent the risk of infection in minor cuts, scrapes, and burns

Warnings For external use only

Do not use
• in or near the eyes • over large areas of the body • on individuals who are allergic or sensitive to iodine

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 one week unless directed by a doctor

Stop use and ask a doctor if • condition persists or gets worse • irritation or redness 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 wipe to affected area 1 to 3 times daily
• may be covered with a sterile bandage • discard wipe after single use

Other information • store at room temperature: 15-30° C (59-86° F)


• do not use if package is torn or open • do not use on individuals who are allergic or sensitive to iodine

Inactive ingredients nonoxonyl-9, water

Questions or comments? 1-800-430-5490



PAWS
Principal Display Panel

 Safetec

NDC 61010-3111-1

P.A.W.S.[®]
Antimicrobial Hand Wipe

Kills 99.99% of Germs!
Enriched with Aloe Vera

Fresh Scent

1 Premoistened Towelette • For Professional Use

SAFETEC OF AMERICA, Inc.

Buffalo, NY 14215 800-456-7077 www.safetec.com

0054

4385 Kit Label
346100



APPROVED
By Rodrigo Rosas Atllano at 2:54 pm, Mar 11, 2019

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
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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: 059QF0K00R)	

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
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Route of Administration	TOPICAL
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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: 059QF0K00R)	

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
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Route of Administration	OPHTHALMIC
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WATER (UNII: 059QF0K00R) (WATER - UNII:059QF0K00R)	WATER	98.6 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
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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: 059QF0K00R)	
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)

Revised: 10/2019

Honeywell Safety Products USA, Inc.