

4279 FIRST AID KIT - 4279 first aid kit
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.

4279 First Aid Kit (Burn Jel, FABC, EW, triple, BZKI wipes, ammonia- SF00002196)

First Aid Burn Cream

Active ingredient

Benzalkonium chloride 0.13%

Lidocaine HCl 0.5%

First Aid Burn Cream

Purpose

First aid antiseptic

External analgesic

First Aid Burn Cream

Uses

- prevent skin infection
- for temporary relief of pain associated with minor burns

First Aid Burn Cream

Warnings

For external use only

Do not use

- in or near the eyes
- if you are allergic to any of the ingredients
- in large areas of the body, particularly over raw surfaces or blistered areas
- for more than 10 days

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
- symptoms persist for more than 7 days or clear up and occurs again within a few days

First Aid Burn Cream

Directions

- **adults and children 2 years of age and older:**
- clean the affected area

- apply a small amount of this product (equal to the surface area of the tip of a finger) onto affected area 1 to 3 times daily
- may be covered with a sterile bandage
- children under 2 years of age: consult a doctor

First Aid Burn Cream

Other information

- tamper evident sealed packets
- do not use if packet is opened or torn

First Aid Burn Cream

Inactive ingredients

aloe barbadensis juice, cetyl alcohol, diazolidinyl urea, edetate disodium, glycerin, glyceryl stearate SE, methylparaben, mineral oil, PEG-100, propylene glycol, propylparaben, stearic acid, trolamine, water

First Aid Burn Cream

Questions

1-800-430-5490

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.

Eyewash***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

Eyewash***Questions***

1-800-430-5490

Triple***Active ingredient (each gram contains)***

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 15⁰ to 25⁰ C (59⁰ to 77⁰ 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 Wipes

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 Wipes

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 Wipes

Other information

store at room temperature 15⁰ to 30⁰ C (59⁰ - 86⁰ F)
do not reuse towelette

BZK Wipes

Inactive ingredient

water

BZK Wipes

Questions

1-800-430-5490

Ammonia

Active ingredient

Ammonia 15%

Ammonia

Purpose

Respiratory stimulant

Ammonia**Uses**

- to prevent or treat fainting

Ammonia**Warnings****For external use only****Do not use**

- if you have breathing problems such as asthma or emphysema

Stop use and ask a doctor if

- condition persists

Keep out of reach of children

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

Ammonia**Directions**

- hold inhalant away from face and crush ampoule between thumb and forefinger at position indicated on sleeve.
- hold near nostrils for inhalation of volatile vapor

Ammonia**Other information**

store at room temperature away from light

Ammonia**Inactive ingredients**

alcohol USP, FD&C red #40, lavender oil, lemon oil fcc, nutmeg oil, purified water

Ammonia**Questions or Comments?**

1-800-430-5490

Burn Jel**Active ingredient**

Lidocaine HCl 2.0 %

Burn Jel**Purpose**

External analgesic

Burn Jel**Uses**

temporarily relieves pain due to minor burns

Burn Jel

Warnings

For external use only

Do not use

- on large areas of the body, particularly over raw surfaces or blistered areas

When using this product

- avoid contact with eyes

Stop use and ask a doctor if

- the condition gets worse
- symptoms persist 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.

Burn Jel

Directions

- adults and children 2 years of age and older; apply to affected area not more than 3 to 4 times daily
- children under 2 years of age: ask a doctor
- you may report a serious reaction to this product to 800-430-5490

Burn Jel

Other information

- store at room temperature
- do not use if opened or torn

Burn Jel

Inactive ingredients

carbopol 940, carbopol 1342, diazolidinyl urea, glycerin, melaleuca alternifolia (tea tree) leaf oil, methylparaben, octoxynol-9, propylene glycol, propylparaben, trolamine, water

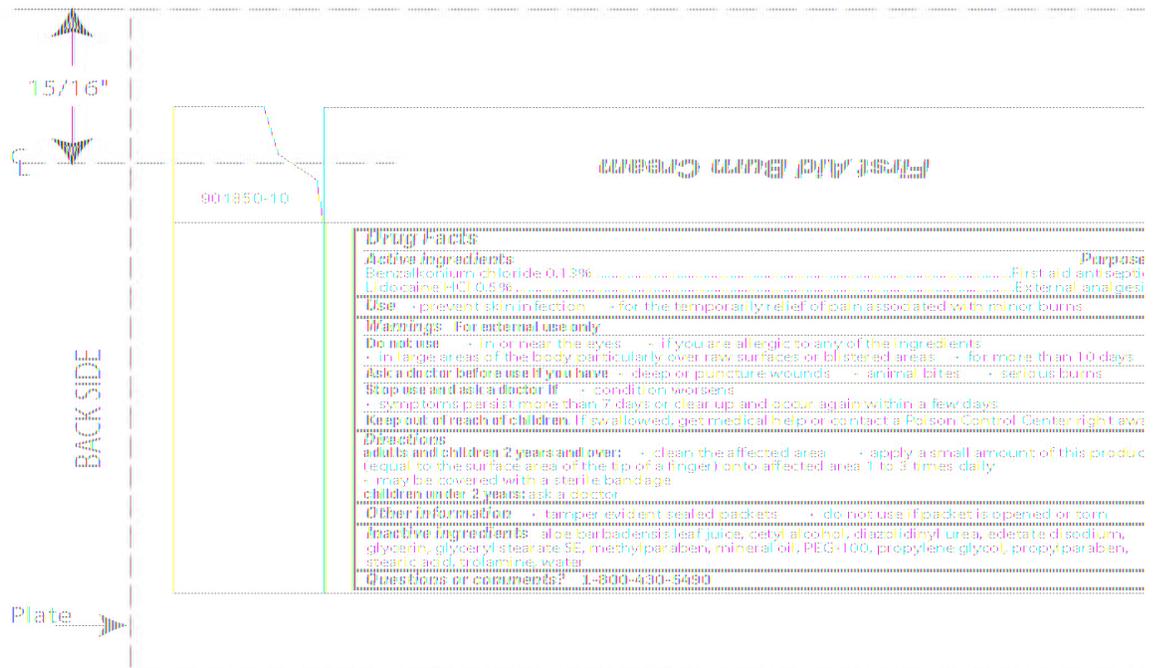
Burn Jel

Questions

1-800-430-5490

First Aid Burn Cream

Principal Display Panel



Principal Display Panel



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 45033 17

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	

space for lot code and supplier part number

PEEL / PELAR / PELER

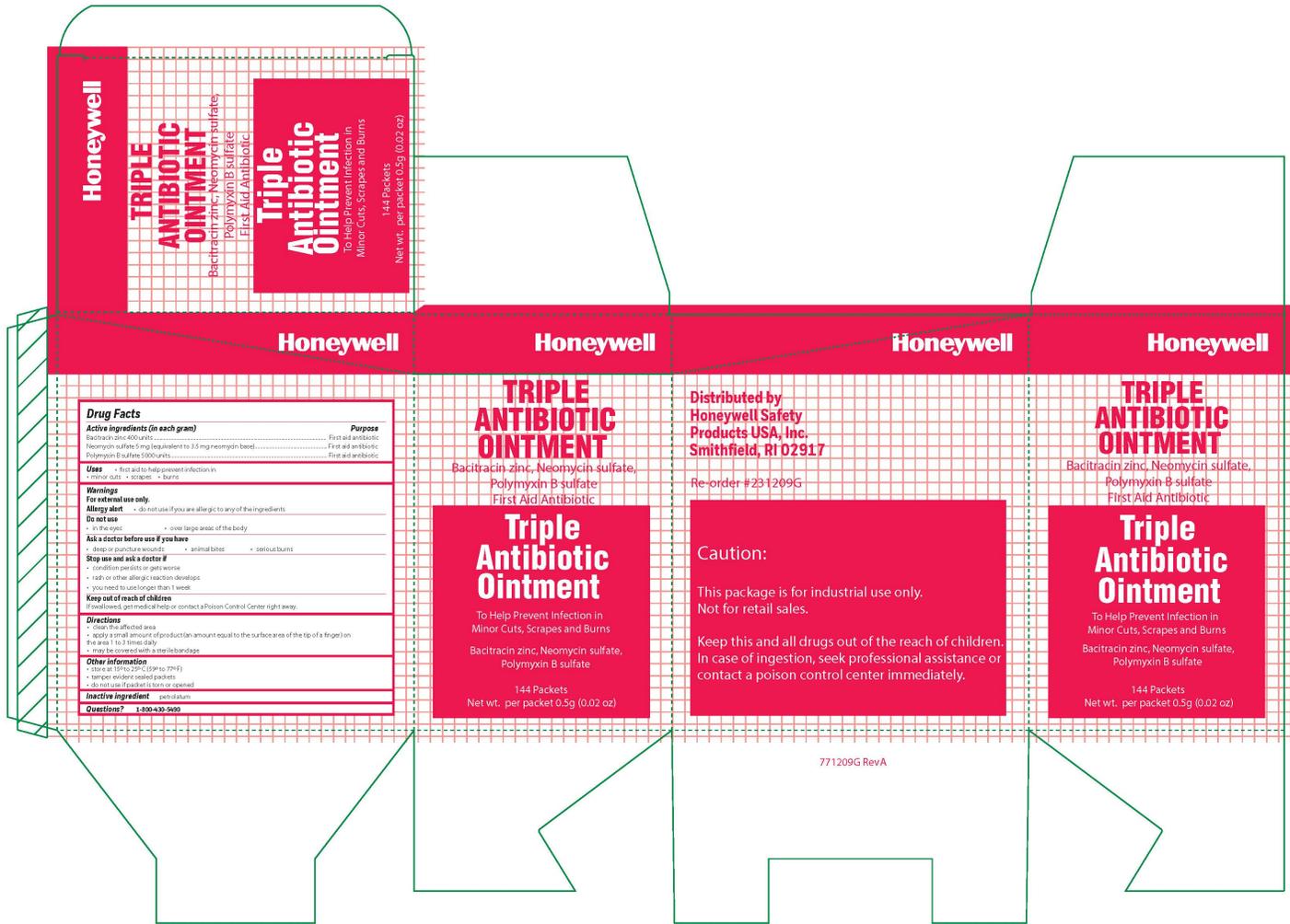
Datos de medicamento (Para EE.UU. solamente)

Ingrediente Activo Agua estéril 99%	Propósito Lavaojos
Usos para el lavado de ojo para quitar las partículas sueltas y extrañas, los contaminantes aéreos, 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 médica 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 en la botella • si es necesario, sigue enjuagado con un lavado 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, jetez-les. 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

Triple Principal Display Panel



Honeywell

**TRIPLE
ANTIBIOTIC
OINTMENT**

Bacitracin zinc, Neomycin sulfate,
Polymyxin B sulfate
First Aid Antibiotic

**Triple
Antibiotic
Ointment**
To Help Prevent Infection in
Minor Cuts, Scrapes and Burns
144 Packets
Net wt. per packet 0.5g (0.02 oz)

Honeywell

Honeywell

Honeywell

Honeywell

Drug Facts

Active Ingredients (in each gram)	Purpose
Bacitracin zinc 400 units	First aid antibiotic
Neomycin sulfate 5 mg (equivalent to 3.5 mg neomycin base)	First aid antibiotic
Polymyxin B sulfate 5000 units	First aid antibiotic

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

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
• deep or puncture wounds • animal bites • serious burns
• conditions such as psoriasis

Stop use and ask a doctor if
• rash or other allergic reaction develops
• you need to use longer than 1 week

Keep out of reach of children.
If swallowed, get medical help or contact a Poison Control Center right away.

Directions
• apply to affected area
• apply a small amount of product (an amount equal to the surface area of the tip of a finger) on the area 1 to 3 times daily.
• may be covered with a sterile bandage.

Other information
• keep out of reach of children (39 to 79°F)
• tamper evident sealed packets
• do not use if packet is broken or opened

Inactive ingredient petrolatum

Questions? 1-800-438-5689

**TRIPLE
ANTIBIOTIC
OINTMENT**

Bacitracin zinc, Neomycin sulfate,
Polymyxin B sulfate
First Aid Antibiotic

**Triple
Antibiotic
Ointment**

To Help Prevent Infection in
Minor Cuts, Scrapes and Burns
Bacitracin zinc, Neomycin sulfate,
Polymyxin B sulfate

144 Packets
Net wt. per packet 0.5g (0.02 oz)

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

Re-order #231209G

Caution:

This package is for industrial use only.
Not for retail sales.

Keep this and all drugs out of the reach of children.
In case of ingestion, seek professional assistance or
contact a poison control center immediately.

**TRIPLE
ANTIBIOTIC
OINTMENT**

Bacitracin zinc, Neomycin sulfate,
Polymyxin B sulfate
First Aid Antibiotic

**Triple
Antibiotic
Ointment**

To Help Prevent Infection in
Minor Cuts, Scrapes and Burns
Bacitracin zinc, Neomycin sulfate,
Polymyxin B sulfate

144 Packets
Net wt. per packet 0.5g (0.02 oz)

771209G Rev A

**BZK Wipes
Principal Display Panel**

47001083
Rev B

Antiseptic Towelettes

Honeywell

02-16-35MD

Antiseptic Towelettes

Benzalkonium chloride
First aid antiseptic

Six-Saturated Towelettes

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

47001083
Rev B

Antiseptic Towelettes

Honeywell

Drug Facts

Active Ingredient	Purpose
Benzalkonium chloride 0.133% w/v	First aid antiseptic

Uses • antiseptic cleaning of face, hands and body without soap and water. • air dries in seconds

Warnings
For external use only

When using this product • do not use in the eyes or apply over large areas of the body

Ask a doctor before use • in case of deep or puncture wounds, animal bites, or serious burns

Stop use and consult a doctor if

• irritation, redness or other symptoms develop • condition persists or gets worse

Do not use • longer than 1 week unless directed by doctor

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions • tear open packet, unfold and use as washcloth

Other information

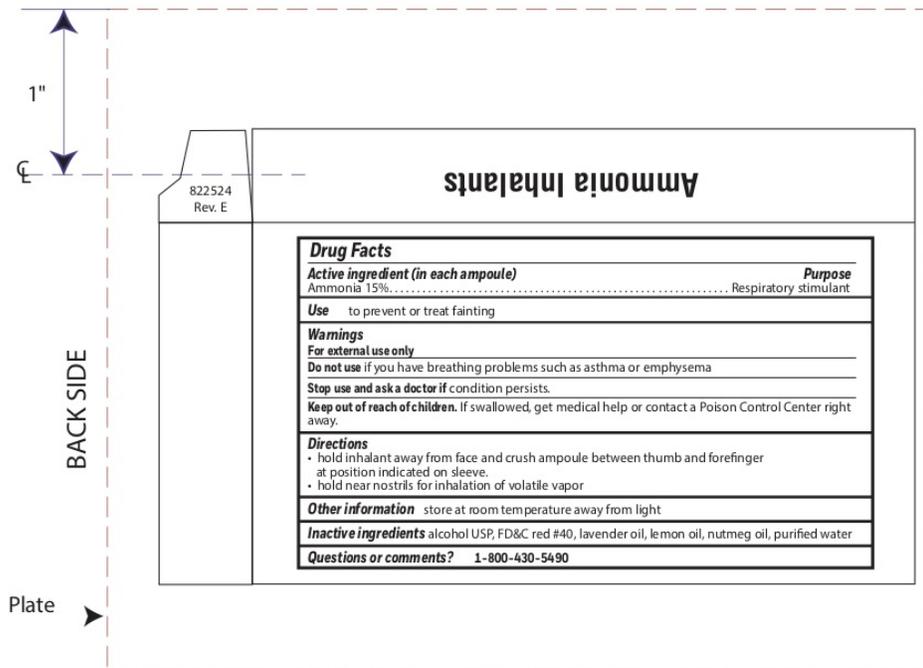
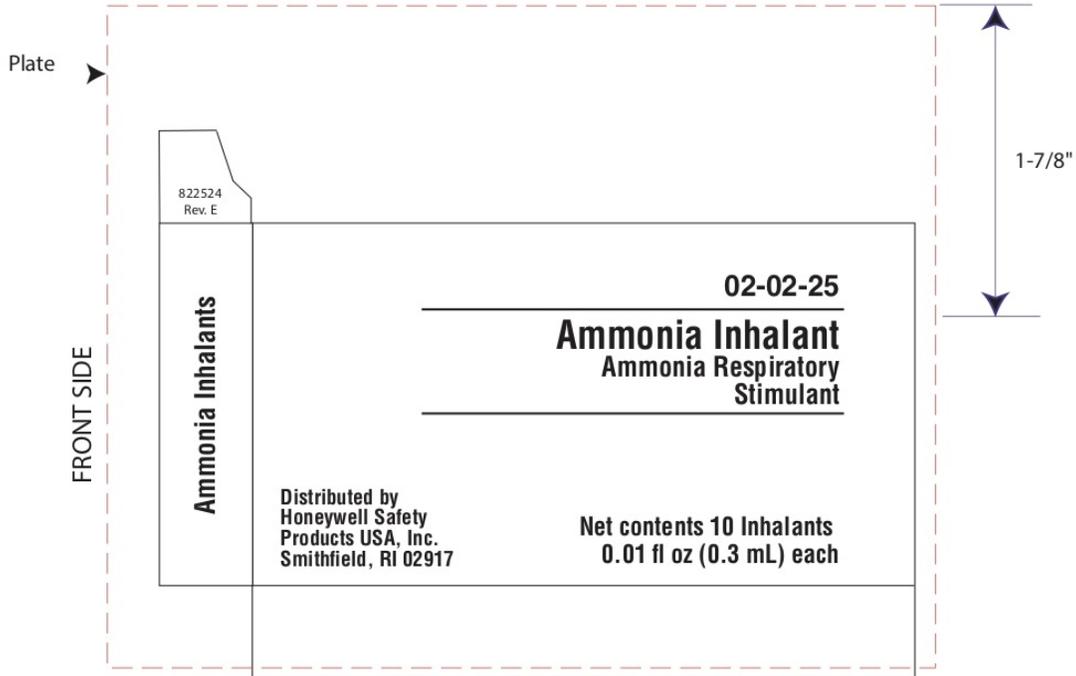
• store at room temperature 15° -30° C (59° -86° F) • do not reuse towelette

Inactive ingredient water

Questions or comments 1-800-430-5490

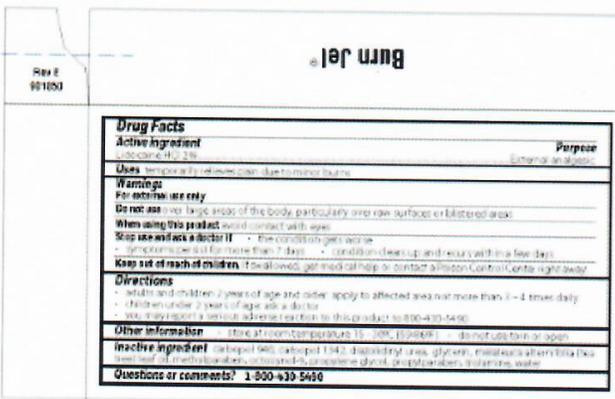
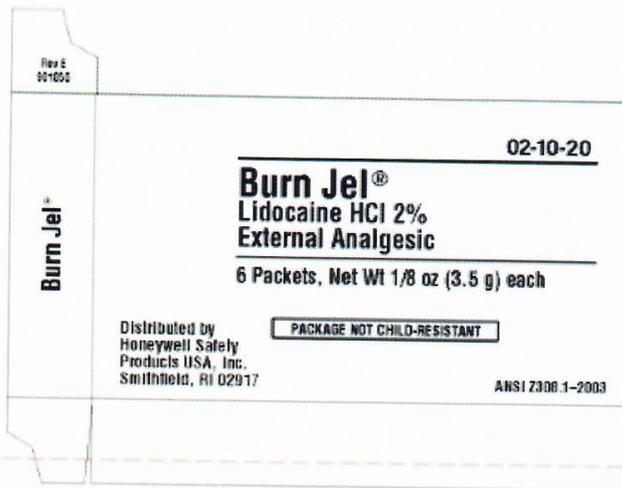
Ammonia
Principal Display Panel

796006 Rev. E Unit Carton Printing Plate for "A" size carton.

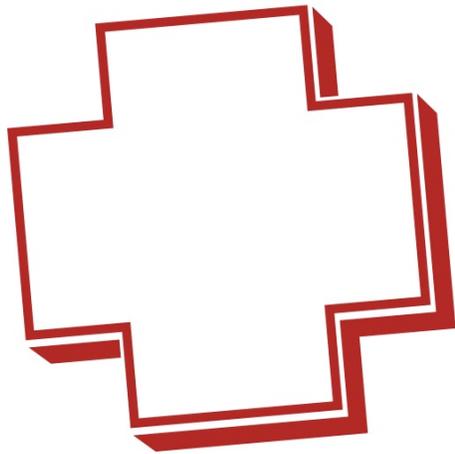


796006 Rev. E (page 3 of 3)

Principal Display Panel



4222 Kit Label
3425PFG



FIRST AID

Each Kit Contains

- | | |
|--|----------------------|
| 1 Plastic Strips
100/Box | 1 Tweezer |
| 1 1/2 x 5 Yd Tape | 1 Scissor |
| 1 5" x 9" Trauma Pad | 1 First Aid Chart |
| 1 2" Gauze Roll | 1 Pair Gloves |
| 1 Triangular Bandage | 5 3" x 3" Gauze Pads |
| 1 First Aid Cream Foil
Packs 10/Box | 2 Eye Pads |
| 1 Cold Pack | 6 Antiseptic Wipes |
| | 2 Ammonia inhalants |
| | 1 1/2 oz Cotton |

25 Econo

Part Number 34-25EF

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

4279

SF00002196 Kit Contents

- 1 SWIFT 1" X 3" PLAS 100/BOX
- 1 TRIPLE ANTIBIOTIC 10 PER
- 1 GAUZE BANDAGE, 4" X 6 YD
- 1 INSTANT COLD PACK 4" X 6"
- 1 BURN JEL 1/8 OZ, 6 PER
- 1 ADHESIVE TAPE W/P 1/2" X 5 YD
- 1 FIRST AID GUIDE ASHI
- 1 GAUZE CLEAN-WRAP BDGE N/S 2"
- 1 ABD COMBINE PAD 5" X 9"
- 1 OZ, BUFF EYEWASH
- 1 SCISSOR BDGE 4" RED PLS HDL
- 1 KIT TWEEZER 3 1/2" SLANTED
- 1 # 25 EMPTY NO LOGO BLANK
- 1 F. A. INST CHART SM (INDIVIDUAL LBL)
- 1 LBL NORTH CONTS 6.75X3.5 ID B
- 1 FIRST AID PACK FOR 25 ECONO
- 1 FIRST AID CREAM FOIL PKS 16/BG
- 1 TRI BNDG NON WOVEN 40"X40"X56"

4279 FIRST AID KIT

4279 first aid kit kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0498-4279
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4279-01	1 in 1 KIT; Type 0: Not a Combination Product	10/18/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	6 PACKET	5.4 g
Part 2	1 BOTTLE	30 mL
Part 3	10 PACKET	9 g
Part 4	6 PACKET	8.4 mL
Part 5	2 AMPULE	0.6 mL
Part 6	6 PACKET	21 g

Part 1 of 6**FIRST AID BURN**

benzalkonium chloride, lidocaine hydrochloride cream

Product Information

Item Code (Source)	NDC:0498-0903
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Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE	0.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
METHYL PARABEN (UNII: A2I8C7HI9T)	

CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	

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
OTC monograph not final	part333A	12/20/2017	

Part 2 of 6

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:0498-0100-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	12/18/2018	

Part 3 of 6

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
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	400 [iU] in 1 g
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	5000 [iU] in 1 g
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:116QD7X297)	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:0498-0750-35	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
OTC monograph final	part333B	09/19/2018	

Part 4 of 6

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: 059QF0K00R)	

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
OTC monograph not final	part333E	12/21/2017	

Part 5 of 6

AMMONIA INHALENT

ammonia inhalent inhalant

Product Information

Item Code (Source) NDC:0498-3334

Route of Administration RESPIRATORY (INHALATION)

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMMONIA (UNII: 5138Q19F1X) (AMMONIA - UNII:5138Q19F1X)	AMMONIA	0.045 g in 0.3 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-3334-00	0.3 mL in 1 AMPULE; 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 6 of 6**BURN JEL**

gel for burns gel

Product Information

Item Code (Source)	NDC:0498-0203
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
TEA TREE OIL (UNII: VIF565UC2G)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
GLYCERIN (UNII: PDC6A3C0OX)	

TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER HOMO POLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0203-00	3.5 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
OTC monograph not final	part348	09/19/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/18/2018	

Labeler - Honeywell Safety Products USA, INC (079287321)

Establishment			
Name	Address	ID/FEI	Business Operations
James Alexander		040756421	manufacture(0498-3334)

Establishment			
Name	Address	ID/FEI	Business Operations
Honeywell Safety Products USA, INC		079287321	pack(0498-4279)

Establishment			
Name	Address	ID/FEI	Business Operations
Water-Jel Technologies		155522589	manufacture(0498-0903, 0498-0750, 0498-0203)

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(0498-0501)