

**4276 FIRST AID KIT- 4276 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.

4276 First Aid Kit (Triple, Burn Jel, PVP wipe- SF00001585)

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

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 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

PVP Wipe

Active ingredient

Povidone-iodine 10%

(equivalent to 1% titratable iodine)

PVP Wipe

Purpose

First aid antiseptic

PVP Wipe

Uses

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

PVP Wipe

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 Wipe

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

4276

SF00001585 Kit Contents

1 TRIPLE ANTIBIOTIC 10 PER

1 TRIANGULAR BDG, NON-STERILE

1 GAUZE PADS, 3" X 3", 4 PER

1 INSTANT COLD PACK 4" X 6"

1 ADHESIVE BDG, PLSTIC, 1" X 3" 16 PER

1 BURN JEL 1/8 OZ, 6 PER

1 PVP IODINE WIPES 10 PER
1 NITRILE GLOVES 2PR BBP
1 TWEEZER PLASTICS 4"
FLEXICON 3"X 4.1 YD 12/BAG
1 FIRST AID GUIDE ASHI
1 SCISSOR BDGE 4" RED PLS HDL
1 BANDAGE COMP 4" W/TELFAPAD 1
LBL STOCK 6-3/8"X4"
LBL STOCK 4"X2-7/8"
1 LBL STOCK 3"x1-7/8"
1 KIT, PP 16 UNIT FA
2 ADHES TAPE EYE STRIPS 2'S
2 EYE PADS STD OVAL STERILE

Burn Jel
Principal Display Panel

796353 Rev. E Unit Carton Printing Plate for "B" size cartor



Principal Display Panel



PVP Wipe Principal Display Panel



PVP Iodine Wipes

NORTH
by Hennepin

02-12-0
ANSI Z395.1-20

Drug Facts (continued)

Ask a doctor before use

- in case of deep or puncture wounds, animal bites, or serious burns

Stop use and ask a doctor if

- irritation persists or gets worse

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

Directions

- clean the affected area
- apply a small amount of the product on the area 1 to 3 times daily
- may be covered with a sterile bandage
- if healed, let dry first

Other information

- do not use on face/wounds who are allergic or sensitive to iodine
- store at room temperature, 15-30° C (59-85° F)
- do not use if pouch is open or torn
- discard after each use

Contains hypochlorite
hexachloroethane

Questions and comments? 1-800-430-4410

PVP Iodine Wipes

NORTH
by Hennepin



PVP Iodine Wipes

Fast-Saturated Wipe

02-12-0
ANSI Z395.1-20

Drug Facts

Active ingredient
Povidone-iodine, 10% (equivalent to 1% Iodine)

Use

- fast and to help prevent the risk of infection in minor cuts, scrapes, and burns

Warnings

- For external use only

When using this product

- do not use in the eyes or apply near large areas of the body
- do not use longer than 1 week unless directed by a doctor

4276 Kit Label
SF00001585



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

4276 FIRST AID KIT

4276 first aid kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0498-4276
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4276-01	1 in 1 KIT	09/13/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	6 PACKET	21 g
Part 2	10 POUCH	3 mL
Part 3	5 PACKET	4.4 g

Part 1 of 3

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
TEA TREE OIL (UNII: VIF565UC2G)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
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	

Part 2 of 3

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: 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 3**TRIPLE ANTIBIOTIC**

bacitracin zinc, polymyxin b sulfate, neomycin sulfate ointment

Product Information

Item Code (Source)	NDC:0498-0750
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Route of Administration	TOPICAL
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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:0498-0750-35	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		
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
Honeywell Safety Products USA, Inc		079287321	pack(0498-4276)

Establishment

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

Establishment

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