4316 FIRST AID KIT- 4316 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.

4316 First Aid Kit (Neomycin, EW, PVP wipes, alcohol wipes, Antiseptic Spray- SF00004530)

Eyes aline

Active ingredient

Sterile Water 99%

Eyesaline

Purpose

Eyewash

Eyes aline

Uses

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

Eyes aline

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.

Eyes aline

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

Eyes aline

Inactive ingredients

sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic

Eyes aline

Questions

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

Povidone Iodine Swab Active ingredient

Povidone-iodine solution USP, 10% (equivalent to 1% titratable iodine)

Povidone Iodine Swab Purpose

First aid antiseptic

Povidone Iodine Swab

Uses

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

Povidone Iodine Swab

Warnings

For external use only

Do not use

- 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 wek unless directed by a doctor

Stop use and ask a doctor if

- conditions persists or gets worse
- irritation and redness develops

Keep out of reach of children

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

Povidone Iodine Swab Directions

Reverse cardboard sleeve, then crush at dot between thumb and forefinger. Allow solution to saturate tip and apply solution to injury.

- clean affected area
- apply to affected area 1 to 3 times daily
- may be covered with a sterile bandage
- discard swab after single use

Povidone Iodine Swab

Other information

- store at room temperature away from light
- keep from freezing or excessive heat
- do not use if package is torn or open

Povidone Iodine Swab Inactive ingredients

citric acid, disodium phosphate,nonoxynol-9, sodium hydroxide, water

Povidone Iodine Swab Questions and comments

1-800-430-5490

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

Do not use

- in the eves
- over large areas of the body

Ask a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burn

When using this product

• do not use longer than one week unless directed by a doctor

Stop use and consult a doctor

• if condition persists or gets worse

Keep out of reach of children

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

Alcohol Wipe

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

Alcohol Wipe Other information

store at room temperature 15 0 to 25 0 C (59 0 to 77 0 F)

Alcohol Wipe Inactive ingredient

water

Alcohol Wipe Questions

1-800-430-5490

Neomycin

Active ingredient

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

Neomycin *Purpose*

First aid antibiotic

Neomycin

Uses

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

Do not use

- in the eyes
- over large areas of the body

Neomycin *Warnings*

For external use only

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

Stop use and ask a doctor if

- a rash or other allergic reaction develops
- you need to use longer than 1 week

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 reach of children

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

Neomycin

Direction

- 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

Neomycin Other information

store at 15 0 to 25 0 C (59 0 to 77 0 F)

Neomycin Inactive ingredient

petrolatum

Neomycin Questions?

1-800-430-5490

Antis eptic Spray Purpose

First aid antiseptic

Antiseptic Spray

Uses

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

Antis eptic Spray *Warnings*

For external use only

Do not use

- in or near the 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 one week unless directed by a doctor

Stop use and ask a doctor if

• 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

Antiseptic Spray

Directions

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

Antis eptic Spray

Other information

- shake well
- store at room temperature 15 0 -30 0 C (59 0 -86 0 F)

Antiseptic Spray

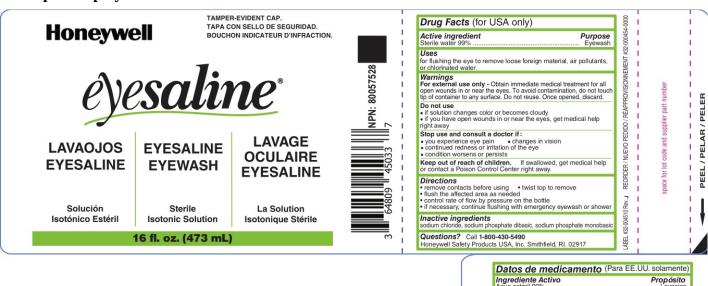
Inactive ingredients

diazolidinyl urea, edetate disodium, glycerin, hypromellose, methylparaben, octoxynol 9, propylene glycol, propylparaben, trolamine, water

Antis eptic Spray *Questions*

1-800-430-5490

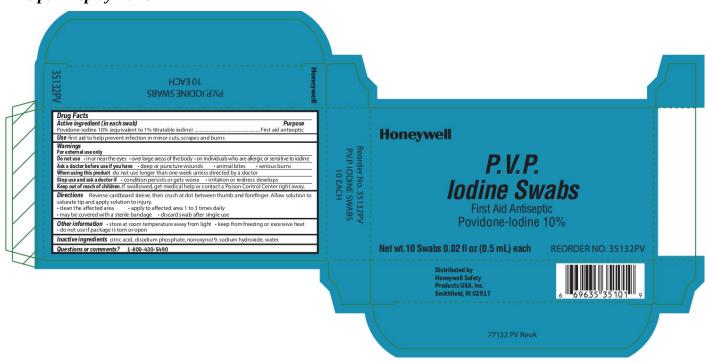
Eyes aline Principal Display Panel



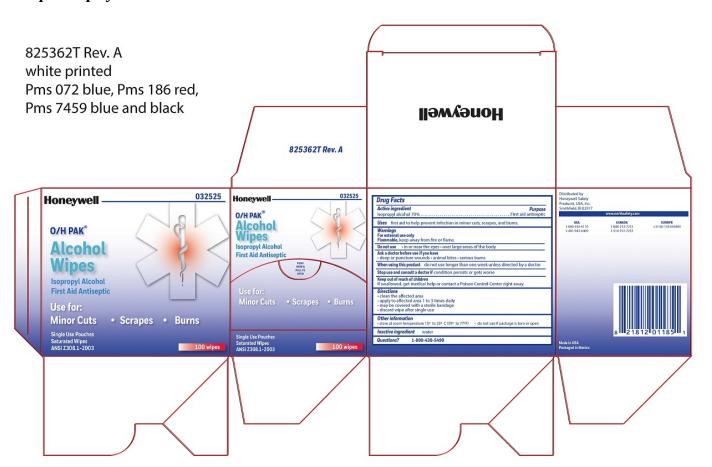




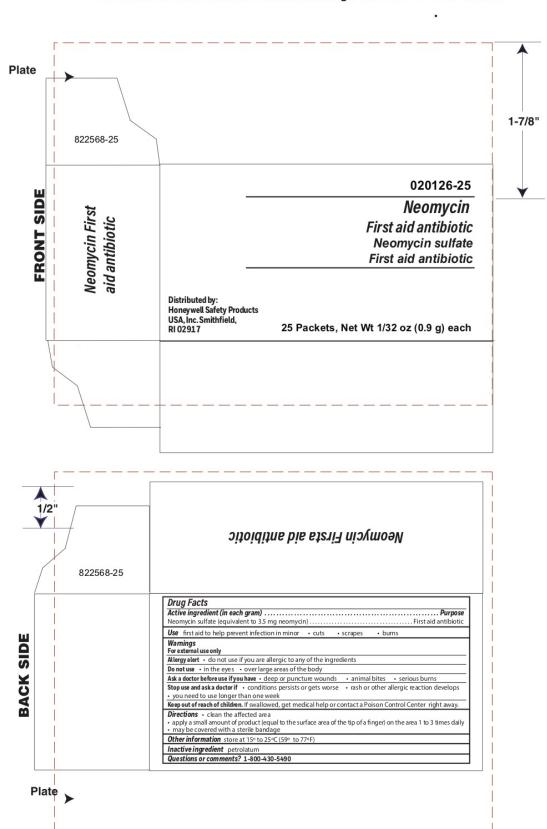
Povidone Iodine Swab Principal Display Panel



Alcohol Wipe Principal Display Panel



796041-25 Rev A Unit Carton Printing Plate for "C" size carton.



Antis eptic Spray Principal Display Panel



4316 Kit Label SF00004530



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

4316 Kit Contnets SF00004530

2 BLUE DETEC FNGERTP 8 WVN 25/B

1 BLUE DETEC KNUCKLE WVN 40/BX

2 BLUE DETEC PLASTIC 1X3 100/B

1 NEOMYCIN ANTIBIOTIC 10 PER

- 1 EYE DRESS PKT W/4 ADH STRIPS
- 2 ALCOHOL PREP PADS 10P
- 4 PVP IODINE WIPES 10 PER
- 1 ADHESIVE TAPE W/P 1/2"X 5 YD
- 1 TWEEZER PLASTICS 4"
- 1 ADH BAND PLSTC EX-LG 25 PER
- 1 O/H PUMP ANTISEPTIC 2 OZ ID F
- 1 FIRST AID GUIDE ASHI
- 4 GAUZE CLEAN-WRAP BDGE N/S 2"
- 4 GAUZE CLEAN-WRAP BDGE N/S 3"
- 1 BLOODSTOPPER
- 1 NON-ADHERENT PADS 2"X3" 10'S
- 1 GZE PADS STERILE 2"X 2" 10'S
- 1 GZE PADS STERILE 3"X 3" 25'S
- 1 ELASTIC BANDAGE 3" X 4.5YD
- 1 CPR FILTERSHIELD 77-100
- 1 4OZ BFS EYEWASH TRILINGUAL BOTTLE
- 1 SCISSOR BDGE 4" RED PLS HDL
- 1 LBL STOCK 6-3/8"X4"
- 1 LBL STOCK 4"X2-7/8"
- 5 PR LRG NITRILE GLVES ZIP BAG
- 1 KIT ST MED FA CABINET-SP SHELF
- 1 TRI BNDG NON WOVEN 40"X40"X56"
- 2 COLD PACK UNIT 4"X6" BULK

4316 FIRST AID KIT

4316 first aid kit kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0498-4316

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# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:0498-4316-01	1 in 1 KIT: Type 0: Not a Combination Product	10 /18 /20 18	

Ω_{112}	ntity	Λf	Parts
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Part #	Package Quantity	Total Product Quantity
Part 1 1 BOTTLE		118 mL

Part 2	20 POUCH	8 mL
Part 3	40 POUCH	12 mL
Part 4	1 BOTTLE, SPRAY	59 mL
Part 5	10 PACKET	9 g

Part 1 of 5

EYESALINE EMERGENCY EYEWASH

purified water liquid

Product Information		
It	tem Code (Source)	NDC:0498-0100
R	toute of Administration	OPHTHALMIC

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

Inactive Ingredients		
Ingredient Name	Strength	
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
SO DIUM PHO SPHATE, DIBASIC (UNII: GR686LBA74)		
SO DIUM PHO SPHATE, MO NO BASIC, MO NO HYDRATE (UNII: 593YOG76RN)		

	Pac	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
l	1 NE	OC: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	12/18/20 18		

Part 2 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	0.7 mL in 1 mL			

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

l	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	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 3 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
PO VIDO NE-IO DINE (UNII: 85H0 HZU99 M) (IO DINE - UNII:9679 TC07X4)	IODINE	10 mg in 1 mL

	Packaging				
l	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l	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 4 of 5

ANTISEPTIC

benzalkonium chloride spray

Product Information	
Item Code (Source)	NDC:0498-0402
Route of Administration	TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
OCTOXYNOL 9 (UNII: 7JPC6Y25QS)			
GLYCERIN (UNII: PDC6A3C0OX)			
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)			
DIPROPYLENE GLYCOL (UNII: E107L85C40)			
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)			
TROLAMINE (UNII: 9O3K93S3TK)			
METHYLPARABEN (UNII: A2I8 C7HI9T)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29 V3WO)			

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:0498-0402- 59	59 mL in 1 BOTTLE, SPRAY; 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	nart333E	09/18/2018	

Part 5 of 5

NEOMYCIN

antibiotic ointment

Product Information

Item Code (Source) NDC:0498-0730

Route of Administration TOPICAL

Active Ingredient/Active Moiety

9	<u> </u>		
	Ingredient Name	Basis of Strength	Strength
NEOMYCIN SULFATE (UN	III: 057Y626693) (NEOMYCIN - UNII:116QD7X297)	NEOMYCIN SULFATE	3.5 mg in 1 g

Inactive Ingredients

ш	U		
		Ingredient Name	Strength
ш			

PETROLATUM (UNII: 4T6H12BN9U)

Packaging

	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:0498-0730-01	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	03/31/2010	

Marketing Information

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

Establishment			
Name	Address	ID/FEI	Business Operations
Honeywell Safety Products USA, INC		079287321	pack(0498-4316)

Establishment			
Name	Address	ID/FEI	Business Operations
Water-Jel Technologies		155522589	manufacture(0498-0730, 0498-0402)

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 Biotext Medical		532775194	manufacture(0498-0121)

Revised: 5/2019 Honeywell Safety Products USA, INC