4349 FIRST AID KIT- 4349 first aid kit
4352 FIRST AID KIT- 4352 first aid kit
4371 FIRST AID KIT- 4371 first aid kit
4374 FIRST AID KIT- 4374 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.

4349, 4352, 4371, 4374 First Aid Kit (Neomycin, HC cr, EW, PVP wipes, Burn Sray, Antiseptic Spray- 018500-4222, 018504-4222, Z018500-4222, Z018504-4222)

Eyesaline
Active ingredient

Sterile Water 99%

Eyesaline
Purpose

Eyewash

Eyesaline
Uses

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

Eyesaline
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.

Eyesaline
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

Eyesaline
Inactive ingredients

sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic

Eyesaline
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

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

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

Do not use
- in the eyes
- over large areas of the body

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

Antiseptic Spray
Active ingredient

Benzalkonium chloride 0.13%

Antiseptic Spray
Purpose

First aid antiseptic

Antiseptic Spray
Uses

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

Antiseptic 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

Antiseptic 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

Antiseptic Spray
Questions

1-800-430-5490

Burn Spray
Active ingredient

Benzethonium chloride 0.2% w/w

Benzocaine 10% w/w

Menthol 0.33% w/w

Burn Spray
Purpose

Benzethonium chloride 0.2% w/w

Benzocaine 10% w/w

Menthol 0.33% w/w

Burn Spray
Uses

for the temporary relief of pain and itching and helps protect against infection in:

- minor cuts and scrapes
- burns
- sunburn
- insect bites
- minor skin irritations

Burn Spray
Warnings

For external use only

Flammable

- keep away from fire or flame
- contents under pressure
- do not puncture or incinerate container
- do not expose to temperatures above 120 0 F

Do not use

- in or near the eyes or other mucous membranes
- in case of serious burns
- in case of deep or puncture wounds
- for prolonged period of time
- on large portion of the body

Stop use and ask a doctor if

- condition worsens or symptoms persist for more than 7 days
- condition clears up and recurs within a few days
- redness, swelling, or irritation occurs

Keep out of the reach of children

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

Burn Spray
Directions

- clean the affected area
- shake can well before using
- hold 4 - 6 inches from surface and spray area until wet
- may be covered with a sterile bandage, if bandaged let dry first
- for adult institutional use only
- not intended for use on children

Burn Spray
Other information

- avoid inhaling
- use only as directed
- intentional misuse by deliberately concentrating or inhaling the contents may be harmful or fatal

Burn Spray
Inactive ingredients

dipropylene glycol, isobutane, n-butane, propane

Hydrocortisone
Active ingredient

Hydrocortisone acetate (equivalent to Hydrocortisone 1%)

Hydrocortisone
Purpose

Anti-itch cream

Hydrocortisone
Uses

- for the temporary relief of itching associated with minor skin irritations and rashes

Hydrocortisone
Warnings

For external use only

Ask a doctor before use if

- you are using any other hydrocortisone product

When using the product

- avoid contact with eyes
- do not begin use of any other hydrocortisone product unless you have consulted a doctor
- do not use for the treatment of diaper rash

Stop use and ask a doctor if
- condition worsens
- condition persists 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.

Hydrocortisone
Directions
- adults and children 2 years and older:
- clean the affected area
- apply to the area not more than 3 to 4 times daily
- children under 2 years of age: consult a doctor

Hydrocortisone
Other information

store at room temperature (do not freeze)

Hydrocortisone
Inactive ingredients

cetyl alcohol, citric acid, diazolidinyl urea, edetate disodium, glycerin, glyceryl monostearate, methylparaben, mineral oil, polyethylene glycol, propylene glycol, propylparaben, purified water, stearic acid, trolamine

Hydrocortisone
Questions or Comments?

1-800-430-5490

4352
018504-4222 Kit Contents

1 1 X 3 WOVEN 100/BOX

1 NEOMYCIN ANTIBIOTIC 10 PER

1 TRIANGULAR BDG, NON-STERILE

1 WIRE SPLINT 1 PER

1 RESCUE BLANKET 1 PER

1 GAUZE COMP, 18" X 36", 2 PER

1 BANDAGE COMP, 2" OFFSET, 4 PER

1 HYDROCORTISON,1.O%,1/32 OZ,10P

1 TWEEZER PLASTICS 4"

4 O/H PAK,ADH BDG 2"X4", X-LG
1 O/H PUMP ANTISEPTIC 2 OZ ID F
1 O/H PUMP BURN RELIEF 2 OZ ID G
1 FIRST AID GUIDE ASHI
1 TAPE ADHESIVE 1"X 5 YD PLSTC
2 GAUZE CLEAN-WRAP BDGE N/S 2"
1 ABD COMBINE PAD 5" X 9"
1 GZE PADS STERILE 3"X 3" 10'S
1 CPR FILTERSHIELD 77-100
10 PVP PREP PADS MEDIUM
1 4OZ BFS EYEWASH TRILINGUAL BOTTLE
1 SCISSOR BDGE 4" RED PLS HDL
LBL STOCK 6-3/8"X4"
LBL STOCK 4"X2-7/8"
1 LBL STOCK 3"x1-7/8"
2 PR LRG NITRILE GLVES ZIP BAG
1 TAPE ADHESIVE 1/2 X 2.5 125133
2 SELF-ADH WRAP 3 X 5 YDS NORTH REV E
1 KIT BAG SOFT PACK LARGE
1 LBL CONTENTS ANSI Z308.1-2009 REV B
2 COLD PACK UNIT 4"X6" BULK
4 EYE PADS STD OVAL STERILE
4 WOVEN FINGERTIP BANDAGE 2"
6 WOVEN KNUCKLE BANDAGE

4371
Z018500-4222 kit contents

1 1 X 3 WOVEN 100/BOX
1 NEOMYCIN ANTIBIOTIC 10 PER
1 TRIANGULAR BDG, NON-STERILE
1 WIRE SPLINT 1 PER
1 RESCUE BLANKET 1 PER
1 GAUZE COMP, 18" X 36", 2 PER
1 BANDAGE COMP, 2" OFFSET, 4 PER
1 HYDROCORTISON,1.O%,1/32 OZ,10P
1 TWEEZER PLASTICS 4"
4 O/H PAK,ADH BDG 2"X4", X-LG

1 O/H PUMP ANTISEPTIC 2 OZ ID F

1 O/H PUMP BURN RELIEF 2 OZ ID G

1 FIRST AID GUIDE ASHI

1 TAPE ADHESIVE 1"X 5 YD PLSTC

2 GAUZE CLEAN-WRAP BDGE N/S 2"

1 ABD COMBINE PAD 5" X 9"

1 GZE PADS STERILE 3"X 3" 10'S

10 PVP PREP PADS MEDIUM

1 4OZ BFS EYEWASH TRILINGUAL BOTTLE

1 SCISSOR BDGE 4" RED PLS HDL

LBL STOCK 6-3/8"X4"

LBL STOCK 4"X2-7/8"

1 LBL STOCK 3"x1-7/8"

2 PR LRG NITRILE GLVES ZIP BAG

2 TAPE ADHESIVE 1/2 X 2.5 125133

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

1 KIT BAG SOFT PACK LARGE

1 LBL CONTENTS ANSI Z308.1-2009 REV B

2 COLD PACK UNIT 4"X6" BULK

4 EYE PADS STD OVAL STERILE

4 WOVEN FINGERTIP BANDAGE 2"

6 WOVEN KNUCKLE BANDAGE

4374 Kit Label
Z018504-4222

Honeywell

First Aid Kit

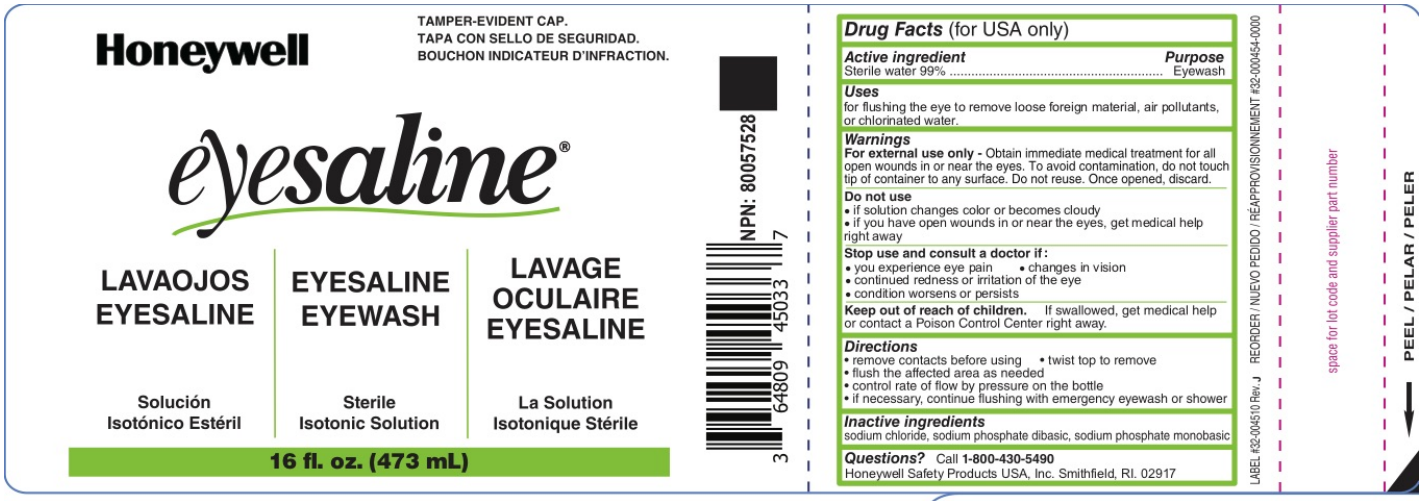
www.honeywellsafety.com

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

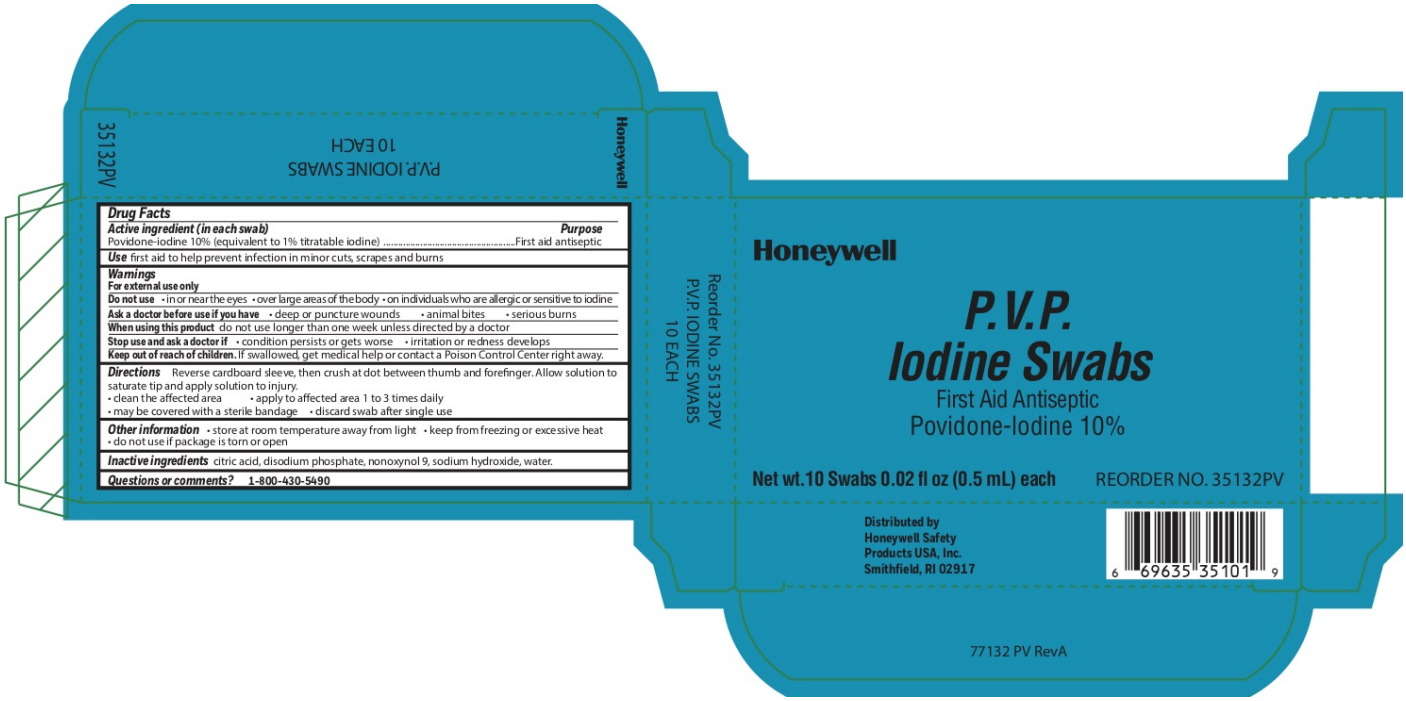
754000 Rev. E

Eyes aline

Principal Display Panel

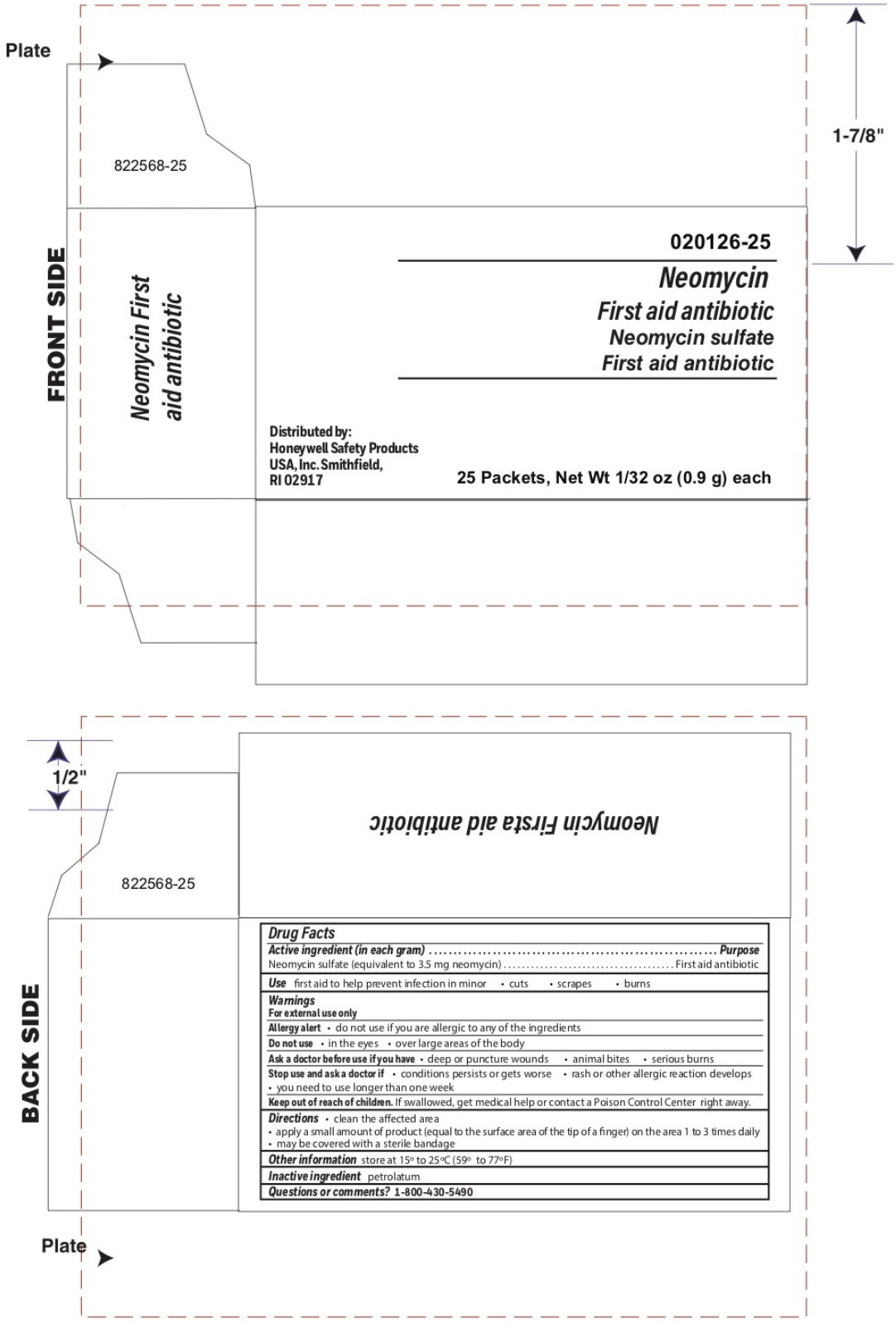


Povidone Iodine Swab
Principal Display Panel



Neomycin
Principal Display Panel

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



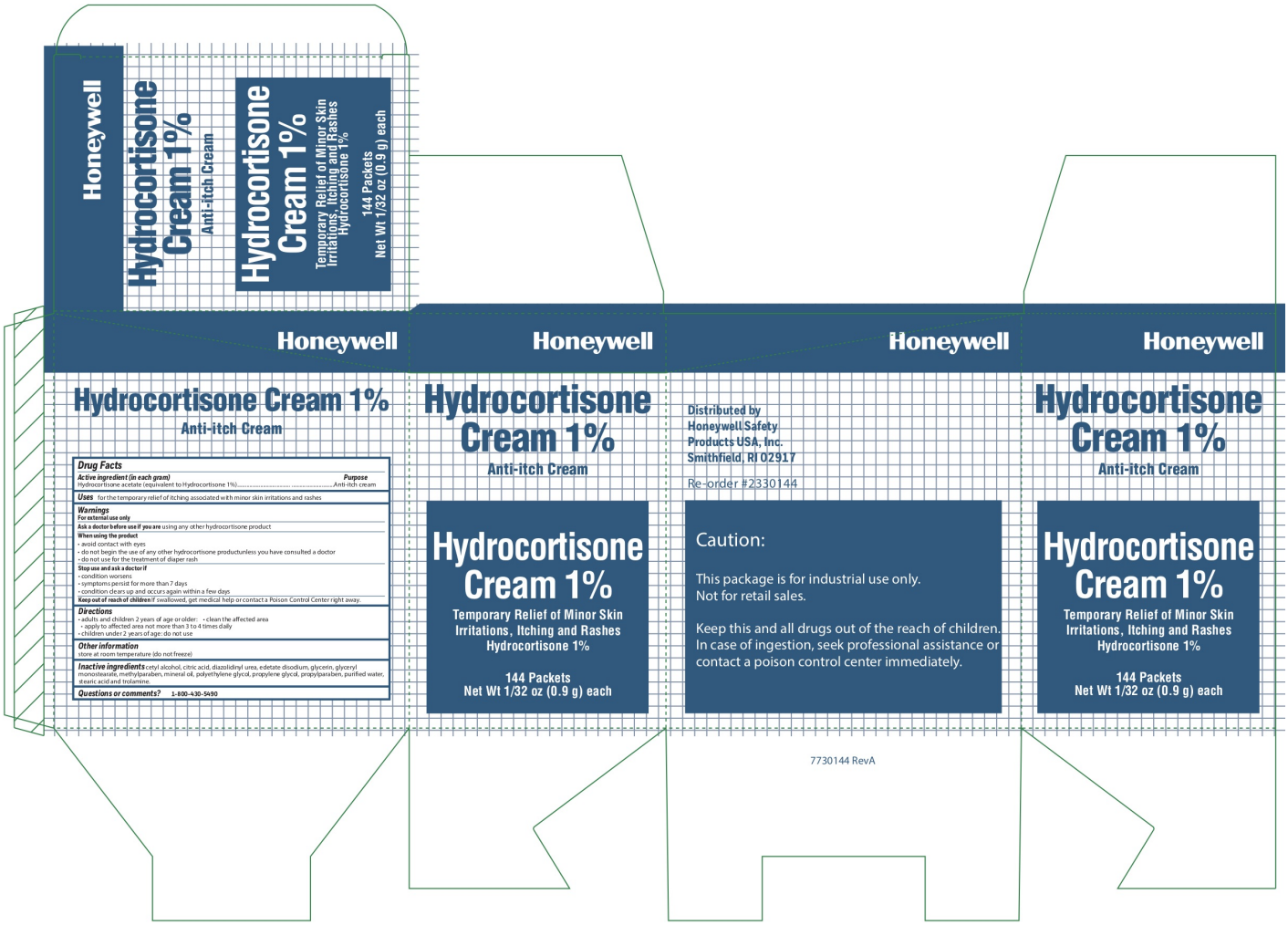
Antiseptic Spray

Principal Display Panel

Burn Spray
Principal Display Panel

Hydrocortisone

Principal Display Panel



4349 Kit Label
0198500-4222

Honeywell

First Aid Kit

www.honeywellsafety.com

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

754000 Rev. E

4349 Kit Contnets

018500-4222

1 1 X 3 WOVEN 100/BOX

1 NEOMYCIN ANTIBIOTIC 10 PER

1 TRIANGULAR BDG, NON-STERILE

1 WIRE SPLINT 1 PER

1 RESCUE BLANKET 1 PER

1 GAUZE COMP, 18" X 36", 2 PER

1 BANDAGE COMP, 2" OFFSET, 4 PER

1 HYDROCORTISON,1.O%,1/32 OZ,10P

1 TWEEZER PLASTICS 4"

4 O/H PAK,ADH BDG 2"X4", X-LG

1 O/H PUMP ANTISEPTIC 2 OZ ID F

1 O/H PUMP BURN RELIEF 2 OZ ID G

1 FIRST AID GUIDE ASHI

1 TAPE ADHESIVE 1"X 5 YD PLSTC

2 GAUZE CLEAN-WRAP BDGE N/S 2"

1 ABD COMBINE PAD 5" X 9"

1 GZE PADS STERILE 3"X 3" 10'S

10 PVP PREP PADS MEDIUM

1 4OZ BFS EYEWASH TRILINGUAL BOTTLE

1 SCISSOR BDGE 4" RED PLS HDL

LBL STOCK 6-3/8"X4"

LBL STOCK 4"X2-7/8"

1 LBL STOCK 3"x1-7/8"

2 PR LRG NITRILE GLVES ZIP BAG

2 TAPE ADHESIVE 1/2 X 2.5 125133

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

1 KIT BAG SOFT PACK LARGE

1 LBL CONTENTS ANSI Z308.1-2009 REV B

2 COLD PACK UNIT 4"X6" BULK

4 EYE PADS STD OVAL STERILE

4 WOVEN FINGERTIP BANDAGE 2"

6 WOVEN KNUCKLE BANDAGE

4352 Kit Label
018504-4222

Honeywell

First Aid Kit

www.honeywellsafety.com

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

754000 Rev. E

4371 Kit Label

Z018500-4222

Honeywell

First Aid Kit

www.honeywellsafety.com

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

754000 Rev. E

4349 FIRST AID KIT

4349 first aid kit kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0498-4349

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0498-4349-01	1 in 1 KIT; Type 0: Not a Combination Product	10/18/2018	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BOTTLE	118 mL
Part 2	10 POUCH	3 mL
Part 3	1 BOTTLE, SPRAY	59 mL
Part 4	1 BOTTLE, SPRAY	59 mL
Part 5	10 PACKET	9 g
Part 6	10 PACKET	9 g
Part 7	10 PACKET	9 g

Part 1 of 7

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

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 2 of 7

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 7

BURN RELIEF

lidocaine hydrochloride spray

Product Information	
Item Code (Source)	NDC:0498-0221
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	24.64 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TEA TREE OIL (UNII: VIF565UC2G)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0498-0221-59	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	part348	09/18/2018	

Part 4 of 7

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 DISODIUM (UNII: 7FLD91C86K)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

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	part333E	09/18/2018	

Part 5 of 7

NEOMYCIN

antibiotic ointment

Product Information	
Item Code (Source)	NDC:0498-0730
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN SULFATE	3.5 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
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	

Part 6 of 7

HYDROCORTISONE

anti-itch cream ointment

Product Information	
Item Code (Source)	NDC:0498-0800
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0800-35	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 not final	part348	03/06/2013	10/15/2019

Part 7 of 7

HYDROCORTISONE

anti-itch cream

Product Information

Item Code (Source)	NDC:0498-0801
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
GLYCERIN (UNII: PDC6A3C0OX)	

WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0801-35	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 not final	part348	10/15/2019	

Marketing Information

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

4352 FIRST AID KIT

4352 first aid kit kit

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0498-4352

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4352-01	1 in 1 KIT; Type 0: Not a Combination Product	10/18/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	118 mL
Part 2	10 POUCH	3 mL
Part 3	1 BOTTLE, SPRAY	59 mL
Part 4	1 BOTTLE, SPRAY	59 mL
Part 5	10 PACKET	9 g
Part 6	10 PACKET	9 g
Part 7	10 PACKET	9 g

Part 1 of 7

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

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 2 of 7

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 7

BURN RELIEF

lidocaine hydrochloride spray

Product Information	
Item Code (Source)	NDC:0498-0221
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	24.64 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

TEA TREE OIL (UNII: VIF565UC2G)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0221-59	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	part348	09/18/2018	

Part 4 of 7

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 DISODIUM (UNII: 7FLD91C86K)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

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	part333E	09/18/2018	

Part 5 of 7

NEOMYCIN

antibiotic ointment

Product Information	
Item Code (Source)	NDC:0498-0730
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN SULFATE	3.5 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	

Part 6 of 7

HYDROCORTISONE

anti-itch cream ointment

Product Information	
Item Code (Source)	NDC:0498-0800
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0498-0800-35	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 not final	part348	03/06/2013	10/15/2019

Part 7 of 7

HYDROCORTISONE

anti-itch cream

Product Information	
Item Code (Source)	NDC:0498-0801
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0498-0801-35	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 not final	part348	10/15/2019	

Marketing Information

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

4371 FIRST AID KIT

4371 first aid kit kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0498-4371

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0498-4371-01	1 in 1 KIT; Type 0: Not a Combination Product	10/18/2018	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BOTTLE	118 mL
Part 2	10 POUCH	3 mL
Part 3	1 BOTTLE, SPRAY	59 mL
Part 4	1 BOTTLE, SPRAY	59 mL
Part 5	10 PACKET	9 g
Part 6	10 PACKET	9 g
Part 7	10 PACKET	9 g

Part 1 of 7

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

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 2 of 7

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 7

BURN RELIEF

lidocaine hydrochloride spray

Product Information	
Item Code (Source)	NDC:0498-0221
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	24.64 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TEA TREE OIL (UNII: VIF565UC2G)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0498-0221-59	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	part348	09/18/2018	

Part 4 of 7

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 DISODIUM (UNII: 7FLD91C86K)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

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	part333E	09/18/2018	

Part 5 of 7

NEOMYCIN

antibiotic ointment

Product Information	
Item Code (Source)	NDC:0498-0730
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN SULFATE	3.5 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
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	

Part 6 of 7

HYDROCORTISONE

anti-itch cream ointment

Product Information	
Item Code (Source)	NDC:0498-0800
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0800-35	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 not final	part348	03/06/2013	10/15/2019

Part 7 of 7

HYDROCORTISONE

anti-itch cream

Product Information

Item Code (Source)	NDC:0498-0801
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
GLYCERIN (UNII: PDC6A3C0OX)	

WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0801-35	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 not final	part348	10/15/2019	

Marketing Information

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

4374 FIRST AID KIT

4374 first aid kit kit

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0498-4374

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4374-01	1 in 1 KIT; Type 0: Not a Combination Product	10/18/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	118 mL
Part 2	10 POUCH	3 mL
Part 3	1 BOTTLE, SPRAY	59 mL
Part 4	1 BOTTLE, SPRAY	59 mL
Part 5	10 PACKET	9 g
Part 6	10 PACKET	9 g
Part 7	10 PACKET	9 g

Part 1 of 7

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

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 2 of 7

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 7

BURN RELIEF

lidocaine hydrochloride spray

Product Information	
Item Code (Source)	NDC:0498-0221
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	24.64 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

TEA TREE OIL (UNII: VIF565UC2G)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0221-59	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	part348	09/18/2018	

Part 4 of 7

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 DISODIUM (UNII: 7FLD91C86K)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

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	part333E	09/18/2018	

Part 5 of 7

NEOMYCIN

antibiotic ointment

Product Information	
Item Code (Source)	NDC:0498-0730
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN SULFATE	3.5 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	

Part 6 of 7

HYDROCORTISONE

anti-itch cream ointment

Product Information	
Item Code (Source)	NDC:0498-0800
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0498-0800-35	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 not final	part348	03/06/2013	10/15/2019

Part 7 of 7

HYDROCORTISONE

anti-itch cream

Product Information

Item Code (Source)	NDC:0498-0801
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0801-35	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 not final	part348	10/15/2019	

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
Honeywell Safety Products USA, INC		079287321	pack(0498-4349, 0498-4352, 0498-4371, 0498-4374)

Establishment

Name	Address	ID/FEI	Business Operations
Water-Jel Technologies		155522589	manufacture(0498-0730, 0498-0402, 0498-0221, 0498-0800, 0498-0801)

Establishment

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

Establishment

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

Revised: 10/2019 Honeywell Safety Products USA, INC