

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 Safety 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 week 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 15⁰ to 25⁰ C (59⁰ to 77⁰ 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 15⁰-30⁰ C (59⁰ -86⁰ 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, 1.0%, 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,1.0%,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

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



3 64809 1145033 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	

LABEL #E2-000610 Rev. J REORDER / NIEVO PEDIDO / REAPPROVISIONNEMENT #E2-00064-0000

space for lot code and supplier part number

PEEL / PELAR / PELE

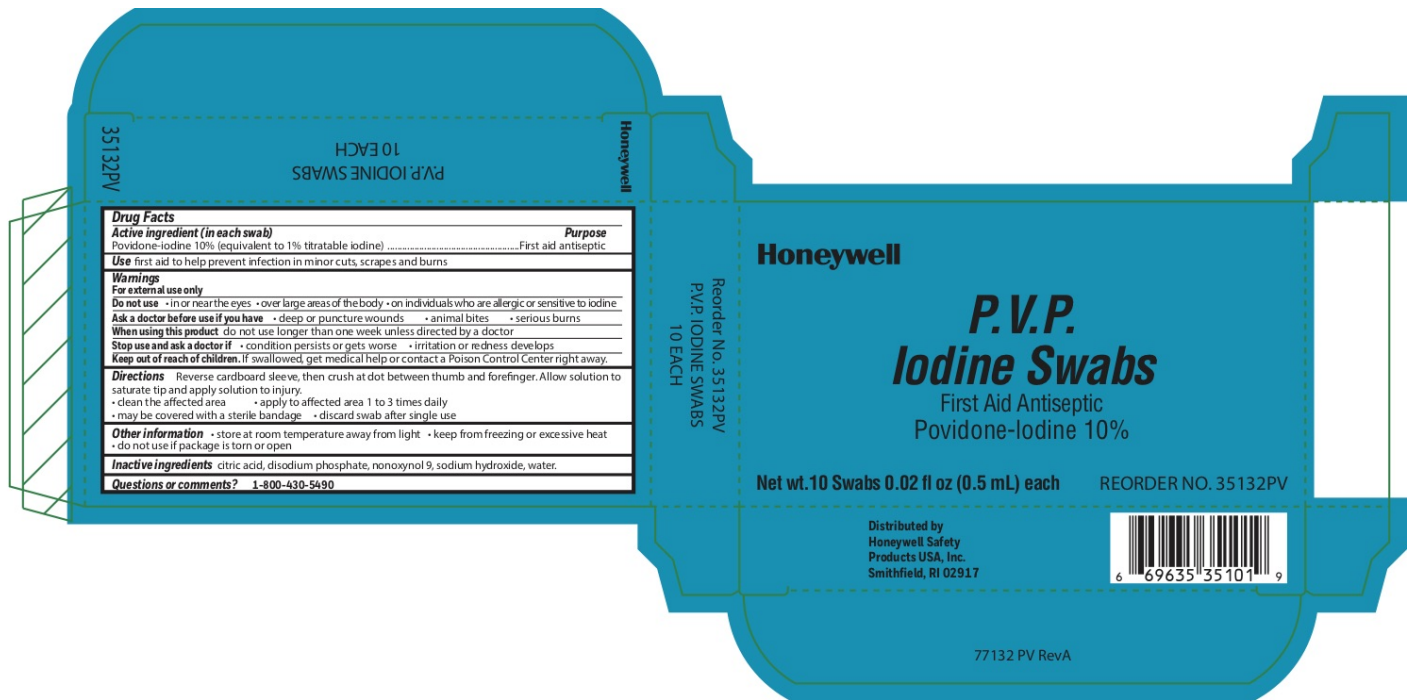
Datos de medicamento (Para EE.UU. solamente)

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

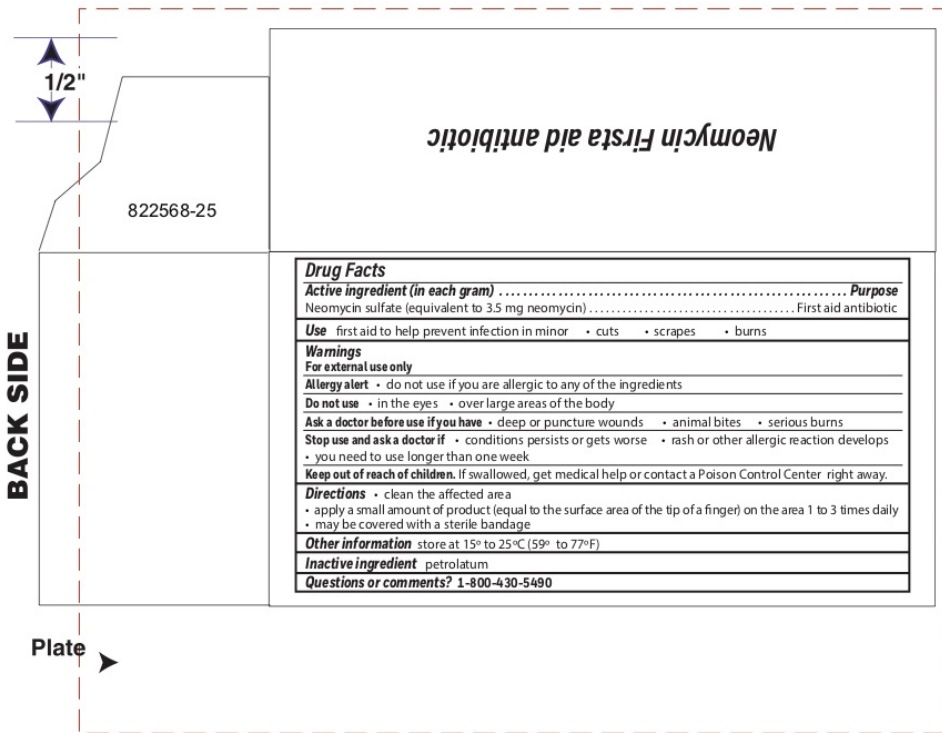
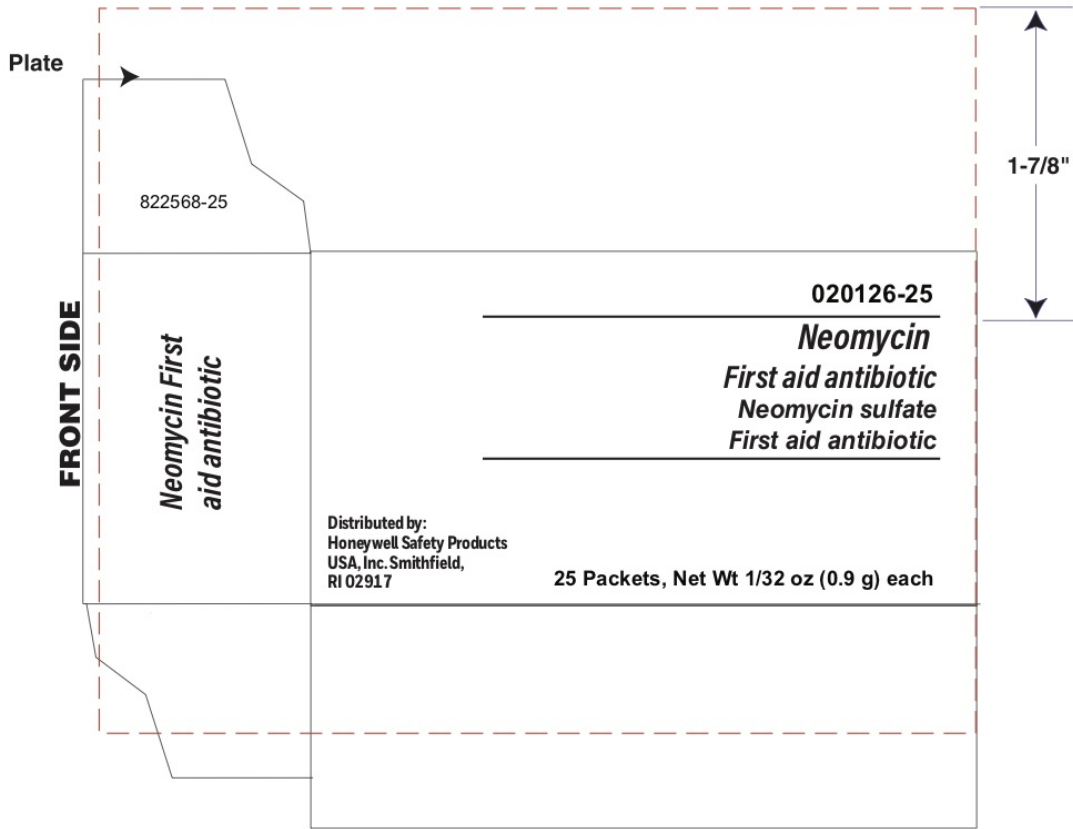
Usages Pour le rinçage des yeux afin d'enlever un corps étranger, des polluants atmosphériques ou de l'eau chlorée.
Advertissements Pour usage externe seulement - Obtenir immédiatement des soins médicaux pour toutes les plaies ouvertes dans ou près des yeux. Pour éviter toute contamination, ne pas toucher 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

Povidone Iodine Swab Principal Display Panel



Neomycin
Principal Display Panel

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



Principal Display Panel

 <p>032203</p> <p>ANTISEPTIC SPRAY</p> <p><i>Benzalkonium chloride</i></p> <p>First Aid Antiseptic</p> <p>Net contents 2 fl oz (59 mL)</p> <p>ANSI Z308.1-2003</p>  <p>8 2 1812 01498 2</p>	<p>Drug Facts</p> <table border="1"> <tr> <th>Active ingredient</th> <th>Purpose</th> </tr> <tr> <td>Benzalkonium chloride 0.13%</td> <td>First aid antiseptic</td> </tr> </table> <p>Uses first aid to help prevent infection in minor cuts, scrapes and burns</p> <p>Warnings For external use only</p> <p>Do not use • in or near the eyes • over large areas of the body</p> <p>Ask a doctor before use if you have • deep or puncture wounds • animal bites • serious burns</p> <p>When using this product do not use longer than one week unless directed by a doctor</p> <p>Stop use and ask a doctor if condition persists or gets worse</p> <p>Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.</p> <p>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</p> <p>Other information • shake well • store at room temperature, 15° to 30°C (59° to 86°F)</p> <p>Inactive ingredients diazolidinyl urea, edetate disodium, glycerin, hypromellose, methylparaben, octoxynol 9, propylene glycol, propylparaben, triethylamine, water</p> <p>Questions or comments? 1-800-430-5490</p>	Active ingredient	Purpose	Benzalkonium chloride 0.13%	First aid antiseptic
	Active ingredient	Purpose			
Benzalkonium chloride 0.13%	First aid antiseptic				
<p><small>Mfg. for: Honeywell Safety Products USA, Inc. Smithfield, RI 02917 002203 Rev. G</small></p>					

Burn Spray Principal Display Panel

Cat. No. 201005

SHAKE WELL BEFORE USING

Honeywell

BURN SPRAY

Water soluble
Benzethonium chloride
Topical antiseptic
Benzocaine
Topical anesthetic
Menthol
Topical anesthetic

Provides antiseptic treatment and helps relieve the pain of minor burns and sunburn.

CAUTION: FLAMMABLE
Contents under pressure
Read warning on back panel.

NET WT. 3 OZ (85gm.)

47.0306

DRUG FACTS	
Active ingredients	Purpose
Benzethonium chloride 0.2% w/w	Topical antiseptic
Benzocaine 1.0% w/w	Topical anesthetic
Menthol, 3.3%	Topical anesthetic
Uses • for the temporary relief of pain and itching and helps to protect against infection in • minor cuts and scrapes • burns • sunburn • insect bites • minor skin irritations	
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°F	
Do not use • in or near eyes or other mucous membranes • in case of serious burns • in case of deep or puncture wounds • for a prolonged period of time • on large portion of the body	
Stop use and ask a doctor if: • conditions 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 reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
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	
Other information • avoid inhaling • use only as directed • intentional misuse by deliberately concentrating and inhaling the contents may be harmful or fatal	
Inactive ingredients dipropylene glycol, isobutane, n-butane, propane	
Questions or comments? 1-800-430-5490	



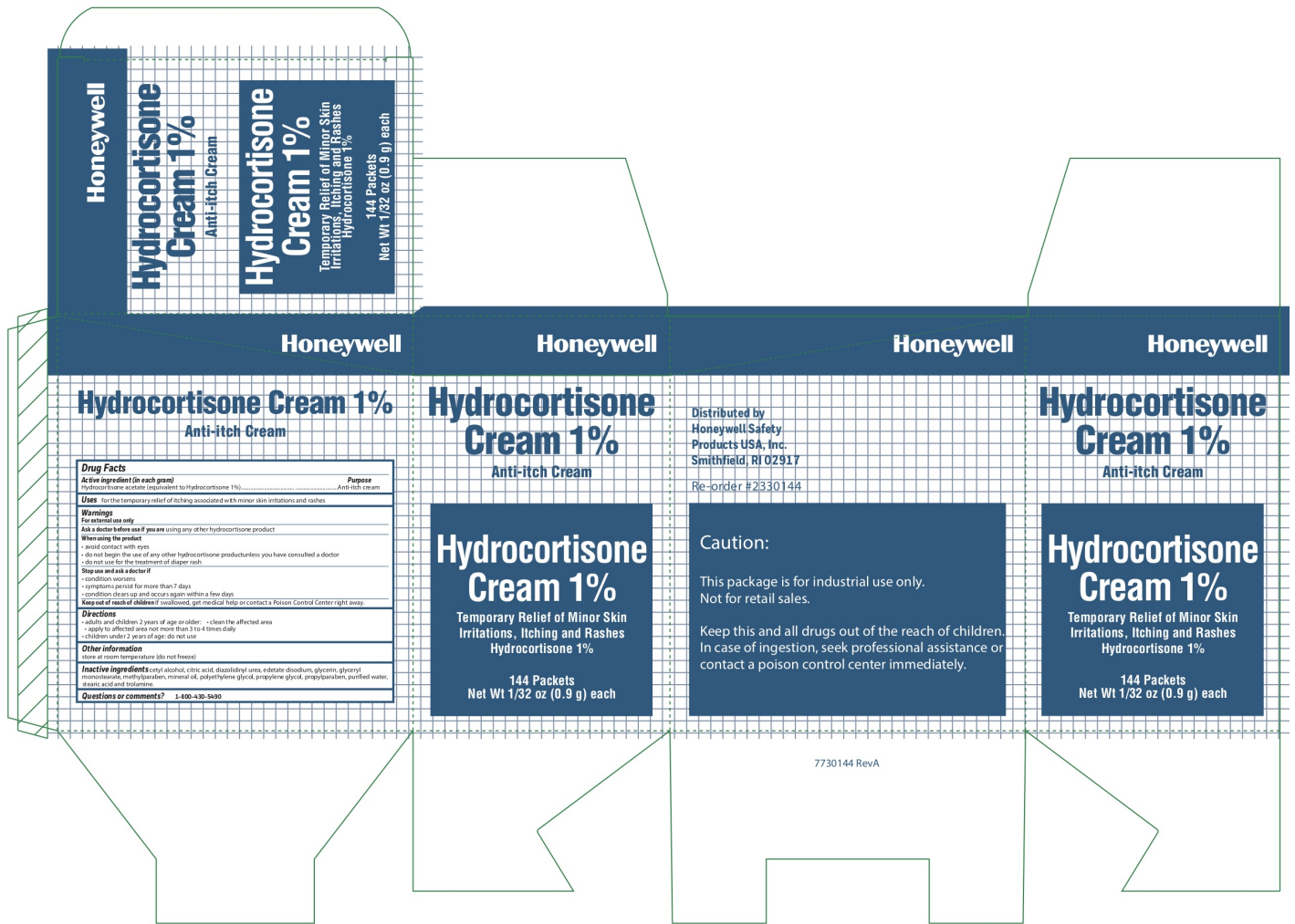
6 69635 20032 4

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

Honeywell

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

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,1.0%,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

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
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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: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0121-00	0.3 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/18/2018	

Part 3 of 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: 059QF0K00R)	
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)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (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:116QD7X297)	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:W14X0X7BPJ)	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)	
METHYL PARABEN (UNII: A2I8C7HI9T)	

DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)
GLYCERIN (UNII: PDC6A3C0OX)
WATER (UNII: 059QF0K00R)
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:W14X0X7BPJ)	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
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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 OPTHALMIC

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
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)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYL PARABEN (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
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Route of Administration	TOPICAL
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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)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYL PARABEN (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
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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
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Route of Administration	OPHTHALMIC
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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: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0121-00	0.3 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/18/2018	

Part 3 of 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: 059QF0K00R)	
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)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (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:H6QD7X297)	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)	
METHYL PARABEN (UNII: A2I8C7HI9T)	

DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
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:W14X0X7BPJ)	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		Item Code (Source)	
HUMAN OTC DRUG		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: 059QF0K00R) (WATER - UNII:059QF0K00R)	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)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYL PARABEN (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
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Route of Administration	TOPICAL
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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)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYL PARABEN (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