4203 FIRST AID KIT- 4203 first aid kit
4256 FIRST AID KIT- 4256 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.

0498-4203, 4256: First Aid Kit (Neomycin, EW, PVP wipes, alcohol wipes, Burn Sray, Antiseptic Spray, aypanal- 019720-0009L, Z019720-0009L)

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

Alcohol Wipe
Active ingredient

Isopropyl alcohol 70%

Alcohol Wipe
Purpose

First aid antiseptic

Alcohol Wipe
Uses

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

Alcohol Wipe
Warnings

For external use only

Do not use

- in the eyes
- over large areas of the body

Ask a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burn

When using this product

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

Stop use and consult a doctor

- if condition persists or gets worse

Keep out of reach of children

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

Alcohol Wipe
Directions

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

Alcohol Wipe

Other information

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

Alcohol Wipe
Inactive ingredient

water

Alcohol Wipe
Questions

1-800-430-5490

Aypanal
Active ingredient

Acetaminophen 325 mg

Aypanal
Purpose

Pain reliever/ fever reducer

Aypanaly
Uses

- temporarily relieves minor aches and pains due to the common cold and headache - temporarily reduces fever

Keep out of reach of children.

Keep out of reach of children.

Aypanal
Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4,000 mg in 24 hours, which is the maximum daily amount
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product:

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters

- rash
- If a skin rash occurs, stop use and seek medical help right away.

Do not use
- with any other drug containing acetaminophen (prescription or nonprescription).
- If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if you have
- liver disease

Ask a doctor or pharmacist before use if
- you are taking the blood thinning drug warfarin

Stop using and ask a doctor if
- pain gets worse or lasts more than 10 days in adults
- pain gets worse or lasts more than 5 days in children under 12 years
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

If pregnant or breast-feeding

If pregnant or breast-feeding, ask a health professional before use.

Overdose warning
- In case of accidental overdose, get medical help or contact a Poison Control Center right away.
- Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Aypanal
Directions

do not take more than directed (see overdose warning)

adults and children 12 years of age or older
- take two tablets every 4-6 hours while symptoms last
- do not take more than 12 tablets in 24 hours

children 6 to under 12 years of age
- take 1 tablet every 4-6 hours while symptoms last
- do not take more than 5 tablets in 24 hours

children under 6 years consult a doctor

Aypanal
Other information

- store at room temperature 15 ^{0} to 30 ^{0} C (59 ^{0} - 86 ^{0} F)
- TAMPER EVIDENT PACKETS- DO NOT USE IF OPEN OR TORN

Aypanal
Inactive ingredients

corn starch, microcrystalline cellulose, povidone, sodium starch glycolate, stearic acid

Aypanal
Questions

1-800-430-5490

Neomycin
Active ingredient

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

Neomycin
Purpose

First aid antibiotic

Neomycin
Uses

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

Do not use

- in the eyes
- over large areas of the body

Neomycin
Warnings

For external use only

Do not use

- in the eyes
- over large areas of the body

Ask a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burns

Stop use and ask a doctor if

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

Stop use and ask a doctor if

- the condition persists or gets worse
- a rash or other allergic reaction develops
- you need to use longer than 1 week

Keep out of reach of children

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

Neomycin
Direction

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

Neomycin
Other information

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

Neomycin
Inactive ingredient

petrolatum

Neomycin
Questions?

1-800-430-5490

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

4256
Z019720-0009L Kit Contents

2 1X3 PLASTIC 100/BOX

1 FINGERTIP "T" WOVEN 40/BOX

1 SWIFT KNUCKLE 40/BX

1 3/4 X 3 WOVEN 100/BOX

1 NEOMYCIN ANTIBIOTIC 10 PER

1 EYE DRESS PKT W/4 ADH STRIPS

2 ALCOHOL PREP PADS 10P

4 PVP IODINE WIPES 10 PER

1 TWEEZER PLASTICS 4"

1 ADH BAND PLSTC EX-LG 25 PER

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

4 GAUZE CLEAN-WRAP BDGE N/S 2"

4 GAUZE CLEAN-WRAP BDGE N/S 3"

1 BLOODSTOPPER

1 NON-ADHERENT PADS 2"X3" 10'S

1 GZE PADS STERILE 2"X 2" 10'S

1 GZE PADS STERILE 3"X 3" 25'S

1 ELASTIC BANDAGE 3" X 4.5YD

1 CPR FILTERSHIELD 77-100

1 AYPANAL NON-ASP IND 2/ENV 100

1 4OZ BFS EYEWASH TRILINGUAL BOTTLE

1 SCISSOR BDGE 4" RED PLS HDL

1 LBL STOCK 6-3/8"X4"

1 LBL STOCK 4"X2-7/8"

5 PR LRG NITRILE GLVES ZIP BAG

1 KIT ST MED FA CABINET-SP SHELF

1 LBL CONTENTS ANSI Z308.1-2009 REV B

1 LBL CAB CVR FA LOGO NORTH ID B

1 TRI BNDG NON WOVEN 40"X40"X56"

2 COLD PACK UNIT 4"X6" BULK

Eyesaline
Principal Display Panel

Honeywell

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 45033 7

Drug Facts (for USA only)

Active ingredient — **Purpose**
Sterile water 99% ..... 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 #32-004510 Rev. J REORDER / NUEVO PEDIDO / RÉAPPROVISIONNEMENT #32-000454-0000

space for lot code and supplier part number

PEEL / PELAR / PELER

Datos de medicamento (Para EE.UU. solamente)

Ingrediente Activo — **Propósito**
Agua estéril 99% ..... Lavaojos

Usos
para el lavado de ojo para quitar las particulas sueltas y extrañas, los contaminantes aeros, 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 medica 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
- quitese 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 el la botella
- si es necesario, sigue enjuagado con un lavaojos 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 atmospheriques oú 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

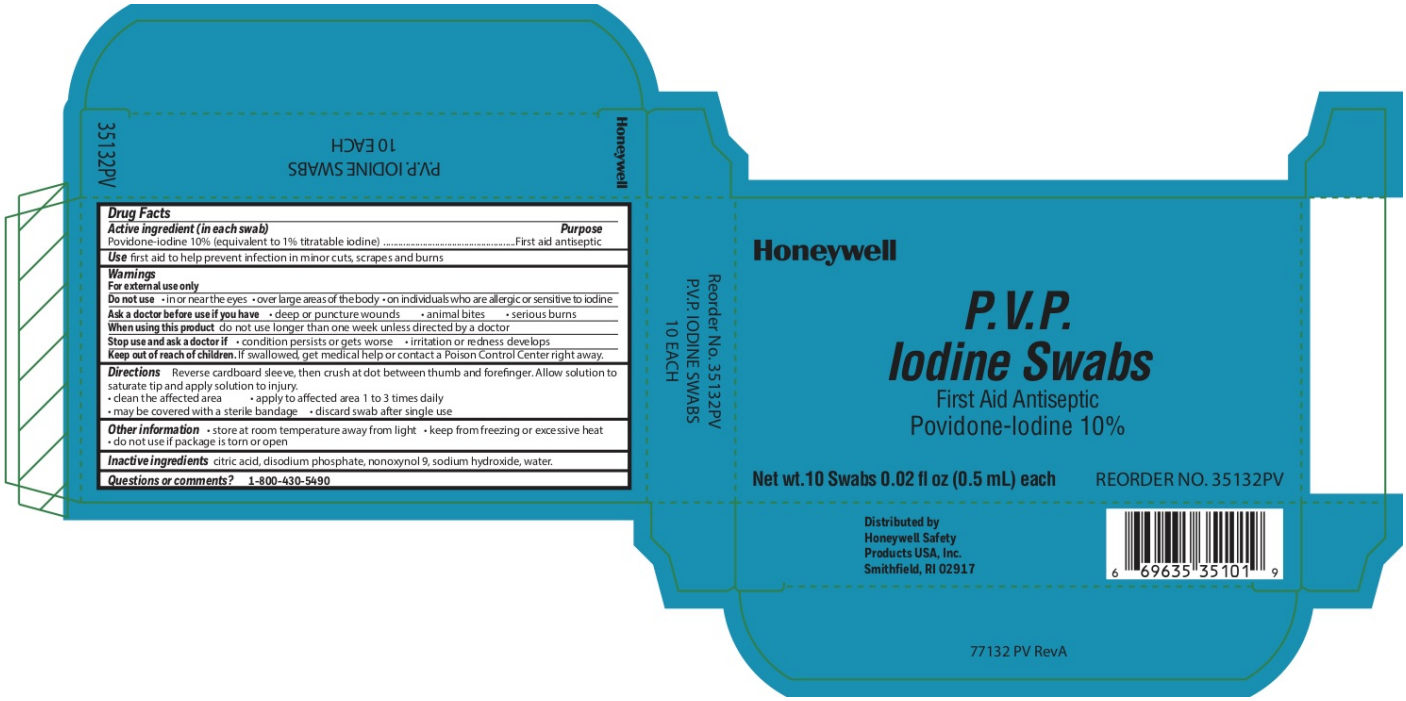
Garder hors de la portée des enfants.
En cas d'ingestion, communiquer immédiatement avec un médecin ou avec un centre antipoison.

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 unesolution de rinçage oculaire d'urgence ou une douche

Ingrédients eau stérile, chlorure de sodium, phosphate dibasique de sodium, phosphate monobasique de sodium

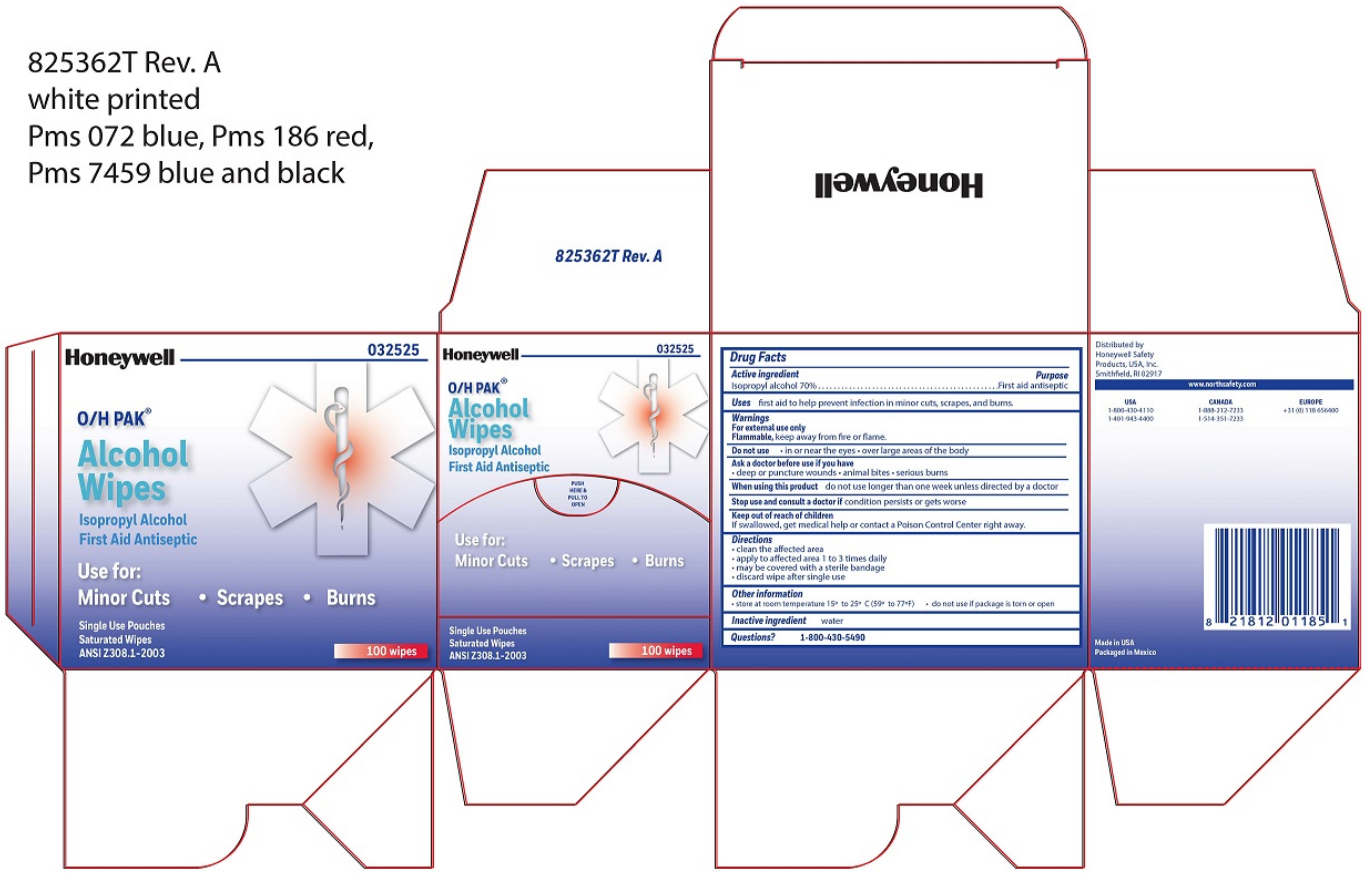
Des questions? Faites le **1-800-430-5490**
Honeywell Safety Products USA, Inc. Smithfield, RI. 02917

Povidone Iodine Swab
Principal Display Panel

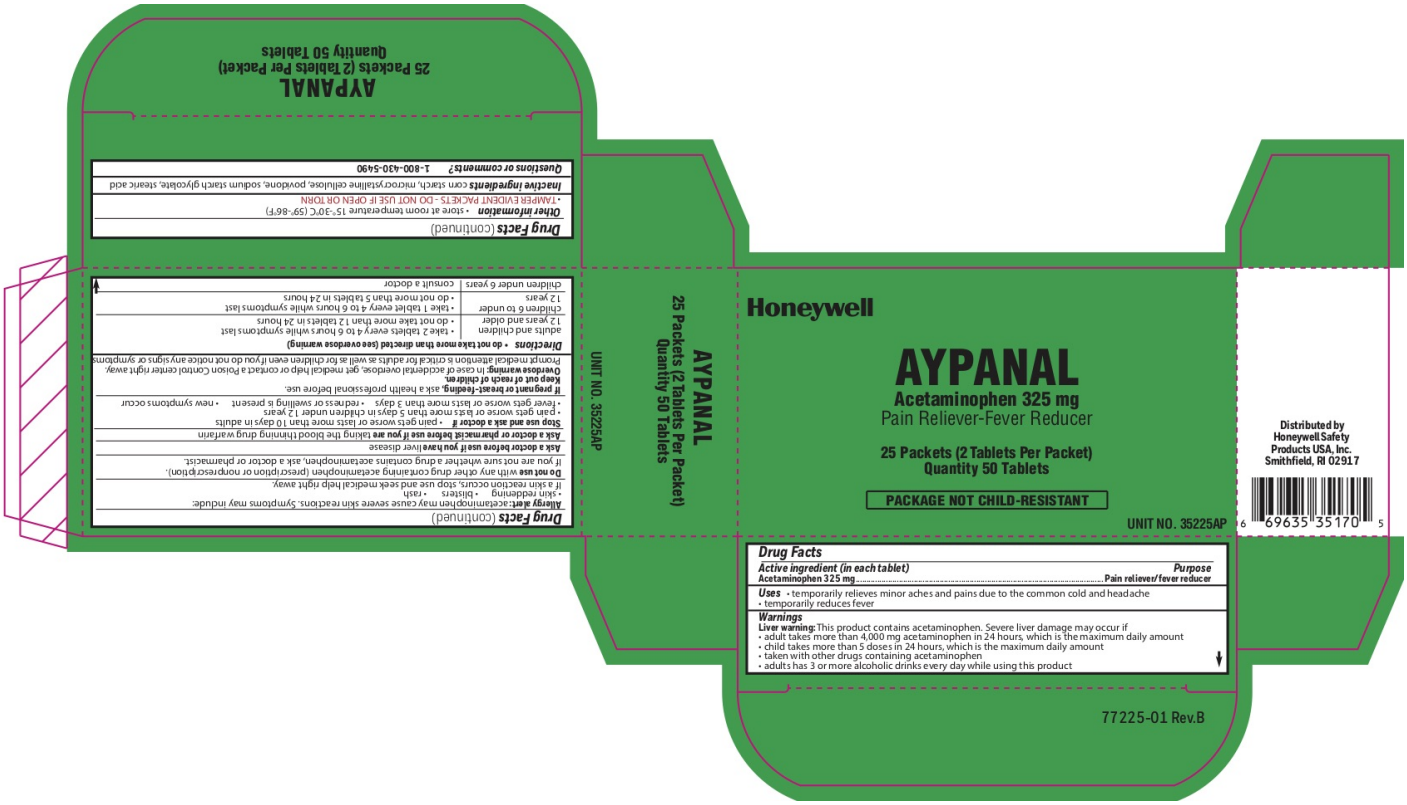


Alcohol Wipe
Principal Display Panel

825362T Rev. A
white printed
Pms 072 blue, Pms 186 red,
Pms 7459 blue and black

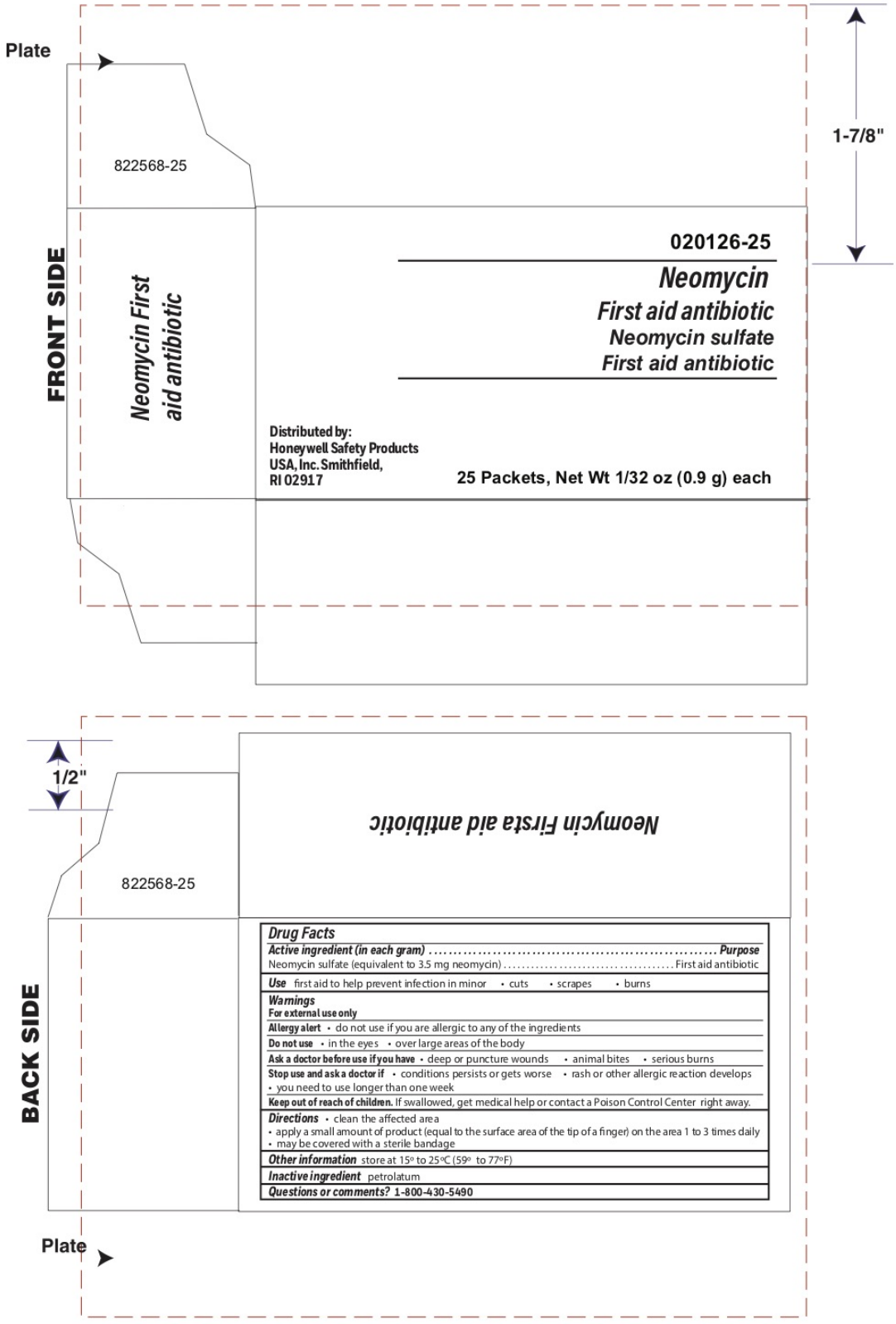


Aypanal
Principal Display Panel



Neomycin
Principal Display Panel

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



Antiseptic Spray

Principal Display Panel

Honeywell 032203

ANTISEPTIC SPRAY

Benzalkonium chloride

First Aid Antiseptic

Net contents 2 fl oz (59 mL)

ANSI Z308.1-2003

8 21812 01498 2

Drug Facts

Active ingredient — **Purpose**
Benzalkonium chloride 0.13% ..... First aid antiseptic

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

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 condition persists or gets worse

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

Directions • clean the affected area
• 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

Other information • shake well
• store at room temperature, 15° to 30°C (59° to 86°F)

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

Questions or comments? 1-800-430-5490

Mfg. for: Honeywell Safety Products USA, Inc. Smithfield, RI 02917 032203 Rev. G

Burn Spray
Principal Display Panel

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

Cat. No. 201005

DRUG FACTS

Active ingredients — **Purpose**
Benzethonium chloride 0.2% w/w ..... Topical antiseptic
Benzocaine 10% 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 mucus 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

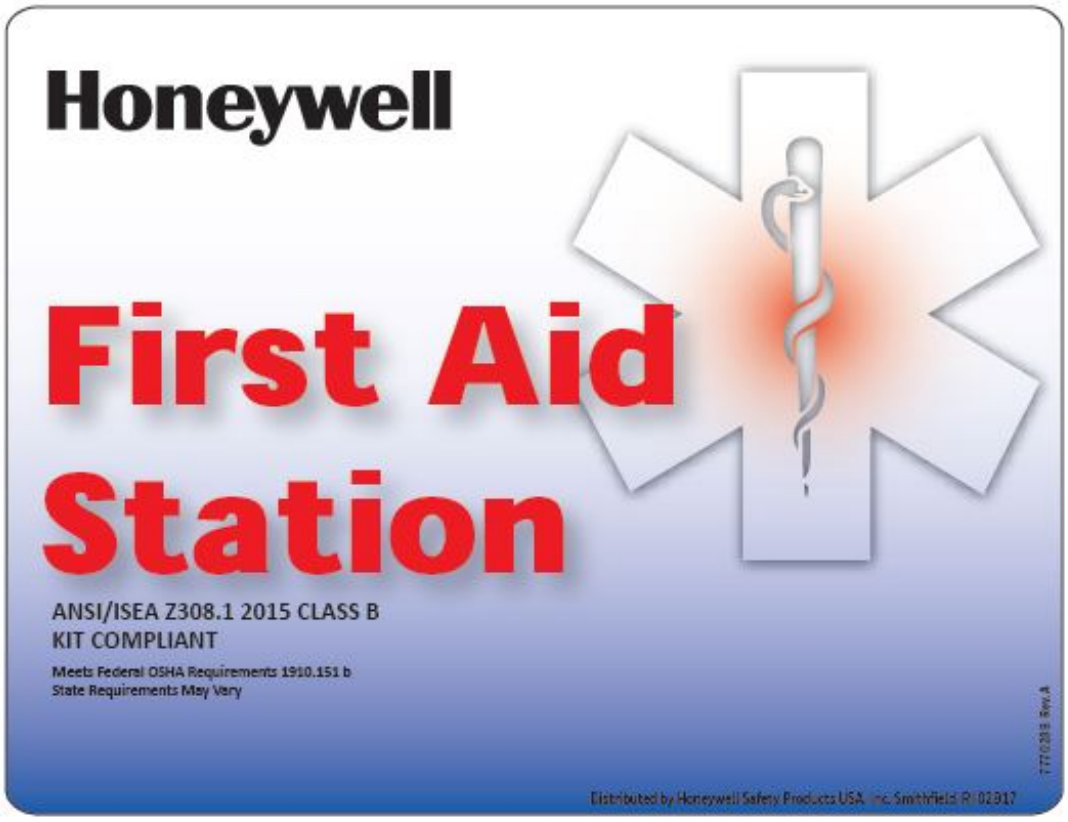
Questions or comments? 1-800-430-5490

6 69635 20032 4

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

Honeywell

4203 Kit Label
019720-0009L



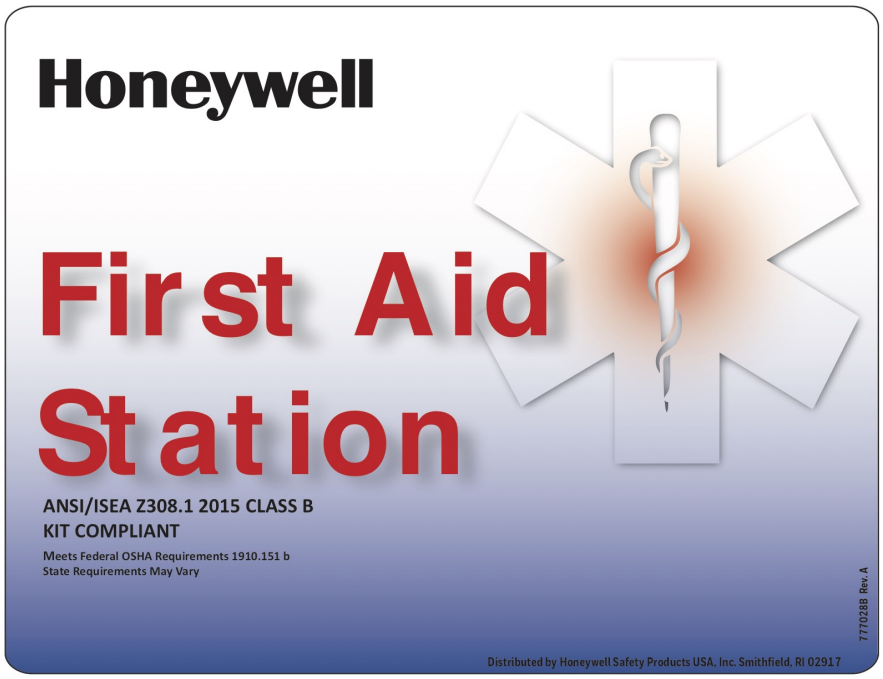
4203 Kit Contnets
019720-0009L

1 1X3 PLASTIC 100/BOX
1 FINGERTIP "T" WOVEN 40/BOX
1 SWIFT KNUCKLE 40/BX
1 3/4 X 3 WOVEN 100/BOX
1 NEOMYCIN ANTIBIOTIC 10 PER
1 EYE DRESS PKT W/4 ADH STRIPS
2 ALCOHOL PREP PADS 10P
4 PVP IODINE WIPES 10 PER
1 TWEEZER PLASTICS 4"
1 ADH BAND PLSTC EX-LG 25 PER
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
4 GAUZE CLEAN-WRAP BDGE N/S 2"
4 GAUZE CLEAN-WRAP BDGE N/S 3"
1 BLOODSTOPPER
1 NON-ADHERENT PADS 2"X3" 10'S
1 GZE PADS STERILE 2"X 2" 10'S
1 GZE PADS STERILE 3"X 3" 25'S

1 ELASTIC BANDAGE 3" X 4.5YD
1 CPR FILTERSHIELD 77-100
1 AYPANAL NON-ASP IND 2/ENV 100
1 4OZ BFS EYEWASH TRILINGUAL BOTTLE
1 SCISSOR BDGE 4" RED PLS HDL
1 5 PR LRG NITRILE GLVES ZIP BAG
1 KIT ST MED FA CABINET-SP SHELF
1 LBL CONTENTS ANSI Z308.1-2009 REV B
1 TRI BNDG NON WOVEN 40"X40"X56"
2 COLD PACK UNIT 4"X6" BULK

4256 Kit Label
Z019720-0009L

777028B Rev. A
white printed four color process
blue (pms 072C) and red (pms 186C)



4203 FIRST AID KIT

4203 first aid kit kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0498-4203

Packaging				
#	Item Code	Package Description	Marketing Start	Marketing End

#	Item Code	Package Description	Date	Date
1	NDC:0498-4203-01	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	20 POUCH	8 mL
Part 3	40 POUCH	12 mL
Part 4	50 PACKET	100
Part 5	1 BOTTLE, SPRAY	59 mL
Part 6	1 BOTTLE, SPRAY	59 mL
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 Drug	M017	12/18/2018	

Part 2 of 7

ALCOHOL WIPE

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:0498-0143
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0498-0143-04	0.4 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

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

Part 3 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 4 of 7

AYPANAL NON-ASPIRIN

acetaminophen tablet

Product Information	
Item Code (Source)	NDC:0498-2001
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients	
Ingredient Name	**Strength**
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	

Product Characteristics			
Color	white	**Score**	2 pieces
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	circle;U
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/10/2012	

Part 5 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
unapproved drug other		09/18/2018	

Part 6 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
unapproved drug other		09/18/2018	

Part 7 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
unapproved drug other		03/31/2010	

Marketing Information

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

4256 FIRST AID KIT

4256 first aid kit kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0498-4256

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4256-01	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	20 POUCH	8 mL
Part 3	40 POUCH	12 mL
Part 4	50 PACKET	100
Part 5	1 BOTTLE, SPRAY	59 mL
Part 6	1 BOTTLE, SPRAY	59 mL
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 Drug	M018	12/18/2018	

Part 2 of 7

ALCOHOL WIPE

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:0498-0143
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0143-04	0.4 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

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

Part 3 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 4 of 7

AYPANAL NON-ASPIRIN

acetaminophen tablet

Product Information	
Item Code (Source)	NDC:0498-2001
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients	
Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	

Product Characteristics			
Color	white	**Score**	2 pieces
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	circle;U
Contains			

Packaging			
#	Item	Package Description	Marketing Start	Marketing End

#	Code	Package Description	Date	Date
1		2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/10/2012	

Part 5 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-	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a		

1	0221-59	Combination Product		

Marketing Information

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

Part 6 of 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
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
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)	

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
unapproved drug other		09/18/2018	

Part 7 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
unapproved drug other		03/31/2010	

Marketing Information

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

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