4304 FIRST AID KIT- 4304 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.

4304 First Aid Kit (ammonia inh, EW, Burn Sray, BZK wipe, triple, ASA- SF00004362)

Eyes aline

Active ingredient

Sterile Water 99%

Eyes aline

Purpose

Eyewash

Eyes aline

Uses

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

Eyes aline

Warnings

For external use only-

Obtain immediate medical treatment for all open wounds in or near eyes.

To avoid contamination, do not touch tip of container to any surface.

Do not reuse. Once opened, discard.

Do not use

- if solution changes color or becomes cloudy
- if you have open wounds in or near the eyes, get medical help right away.

Stop use and ask a doctor if

- you experience eye pain
- changes in vision
- continued redness or irritation of the eye
- condition worsens or persists

Keep out of reach of children

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

Eyes aline

Directions

- remove contacts before using
- twist top to remove

- flush the affected area as needed
- control rate of flow by pressure on the bottle
- if necessary, continue flushing with emergency eyewash or shower

Eyes aline

Inactive ingredients

sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic

Eyes aline

Questions

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

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

<u>Uses</u>

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

Ammonia

Active ingredient

Ammonia 15%

Ammonia

Purpose

Respiratory stimulant

Ammonia

Uses

• to prevent or treat fainting

Ammonia

Warnings

For external use only

Do not use

• if you have breathing problems such as asthma or emphysema

Stop use and ask a doctor if

• condition persists

Keep out of reach of children

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

Ammonia

Directions

- hold inhalant away from face and crush ampoule between thumb and forefinger at position indicated on sleeve.
- hold near nostrils for inhalation of volatile vapor

Ammonia

Other information

• store at room temperature away from light

Ammonia

Inactive ingredients

alcohol USP, FD&C red #40, lavender oil, lemon oil fcc, nutmeg oil, purified water

Ammonia

Questions or Comments?

1-800-430-5490

BZK

Active ingredient

Benzalkonium chloride 0.13% w/v

BZK

Purpose

First aid antiseptic

BZK

Uses

Antiseptic cleansing of face, hands, and body without soap and water

BZK

Warnings

For external use only

Do not use

- in the eyes or over large areas of the body
- on mucous membranes
- on irritated skin
- in case of deep puncture wounds, animal bites or serious burns, consult a doctor
- longer than 1 week unless directed by a doctor

Stop use and ask a doctor if

- if irritation, redness or other symptoms develop
- 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.

BZK

Directions

• tear open packet and use as a washcloth

BZK

Other information

- store at room temperature 15 0 to 30 0 C (59 0 8 0 6 F)
- do not reuse towelette

BZK

Inactive ingredient

water

BZK

Questions

1-800-430-5490

Triple

Active ingredient (each gram contains)

Bacitracin zinc 400 units

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

Polymyxin B sulfate 5000 units

Triple

Purpose

First aid antibiotic

First aid antibiotic

First aid antibiotic

Triple

Uses

first aid to help prevent infection in

- minor cuts
- scrapes
- burns

Triple

Warnings

For external use only

Allergy alert do not use if you are allergic to any of the ingredients

Do not use

- in the eyes
- over large areas of the body

Ask a doctor before use if you have

- a deep or puncture wounds
- animal bites
- serious burns

Stop use and ask a doctor if

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

Keep out of the reach of children

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

Triple

Directions

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

Triple

Other information

- store at 15 0 to 25 0 C (59 0 to 77 0 F)
- tamper evident sealed packets
- do not use if packet is torn or opened

Triple

Inactive ingredient

petrolatum

Triple

Questions

1-800-430-5490

Aspirin

Active ingredient

Aspirin 325 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

As pirin

Purpose

Pain reliever/fever reducer

As pirin

Uses

temporarily reduces fever and relieves minor aches and pains associated with:

- a cold
- headache
- toothache
- muscular aches
- backache
- minor pain of arthritis
- premenstrual and menstrual periods

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

Stomach bleeding warning:

This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher

- if you:are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Do not use

• if you are allergic to aspirin or any other pain reliever/fever reducer

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have a history of stomach problems such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis or kidney disease
- you are taking a diuretic
- you have asthma

Ask a doctor or pharmacist before use if you are

• taking a prescription drug for diabetes, gout or arthritis

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
- feel faint
- vomit blood
- have bloody or black stools
- have stomach pain that does not get better
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- ringing in the ears or loss of hearing occurs
- any new symptoms appear

If pregnant or breast-feeding,

If pregnant or breat-feeding, ask a health professional before use. It is especially important not to use aspirin during the last three months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children.

In case of overdose, get medical help or contact Poison Control Center right away.

Aspirin

Directions

- drink a full glass of water with each dose
- adults and children 12 years of age and older: take 1 or 2 tablets every 4 hours while symptoms last, not more than 12 tablets in 24
- children under 12 years of age consult a doctor

Aspirin

Other information

- store at room temperature 15° 30°C (59° 86°F)
- TAMPER EVIDIENT PACKETS
- DO NOT USE IF OPEN OR TORN

Aspirin

Inactive ingredients

corn starch, croscarmellose sodium*, hypromellose*, microcrystalline cellulose*, mineral oil*, polyethylene glycol*, povidone, propylene glycol, silicon dioxide, stearic acid*, titanium ...

As pirin Questions or comments?

1-800-430-5490

4304 SF00004326 Kit Contents

- 1 1X3 PLASTIC 100/BOX
- 1 FINGERTIP "T" WOVEN 40/BOX
- 1 1X3 WOVEN SING 50/BOX
- 1 SWIFT KNUCKLE 40/BX
- 1 AMMONIA INHALANTS 10 PER
- 1 INSTANT COLD PACK 4" X 6"
- 1 ELASTIC TAPE 1" X 5YD
- 1 O/H TAPE ADHESIVE TRI-CUT
- 1 O/H PUMP BURN RELIEF 2 OZ ID G
- 1 FIRST AID GUIDE ASHI
- 4 GAUZE CLEAN-WRAP BDGE N/S 2"
- 1 BLOODSTOPPER
- 1 GZE PADS STERILE 4"X 4" 10'S
- 1 GZE PADS STERILE 2"X 2" 25'S
- 1 CO-FLEX BANDAGE 2"X 5YDS TAN
- 1 COTTON TIPS 100 PER VIAL
- 1 ANTISEPTIC WIPES BZK CHL 20'S
- 1 ASPIRIN IND PK 5 GR 2/ENV 250
- 1 TRIPLE BIOTIC .5 GRAM PKT 20
- 1 4OZ BFS EYEWASH TRILINGUAL BOTTLE
- 1 SCISSOR BDGE 4" RED PLS HDL
- 1 KIT TWEEZER 3 1/2" SLANTED
- 1 F A KIT EMPTY BLANK 140
- 1 TONGUE BLADES SR WRAPPED 6'S
- 1 LBL STOCK 6-3/8"X4"
- 1 LBL STOCK 4"X2-7/8"
- 1 LBL STOCK 3"x1-7/8"
- 2 PR LRG NITRILE GLVES ZIP BAG
- 2 TRI BNDG NON WOVEN 40"X40"X56"
- 10 NON ADHERENT PAD 2" X 3"
- 1 RED BIO BAGS 2/BX

Isotónico Estéril



Isotonic Solution Isotonique Stérile

16 fl. oz. (473 mL)



Drug Facts (for USA only) Active ingredient 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 right away

Stop use and consult a doctor if:

• you experience eye pain

• continued redness or irritation of the eye

• condition worsens or persists 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 monobasic Questions? Call 1-800-430-5490 Honeywell Safety Products USA, Inc. Smithfield, RI. 02917

> Datos de medicamento (Para EE.UU. solamente) Ingrediente Activo Agua estéril 99% 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
> immediato para todas las heridas abiertas en o cerca de los ojos.
> Para evitar la contaminación, no toque la punta del envase con
> iniguna superficie. No vuelva a usar. Vez abierto, descarbo. 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 de inmediato
>
> Deje de usar y consulte a un médico si:
>
> • experimenta dolor de ojo
> • cambio de visión
> • rojez contiruo o iritación 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
>
> • enjuaque 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, Rl. 02917

LABEL

PEEL / PELAR / PELER

Information

UsagesPour le rinçage des yeux afin d'enlever un corps étranger, des polluants atmospheriques où 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.

ouvert, jetez-les.

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
vous ressentez vune douleur oculaire
vous ressentez vune douleur oculaire
condition empire ou persiste
Carder bore de la nortée de sentante

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 rédusant la pression exercée sur le contenant et in hécelssaire, cominuer de rincer avec unesolution de rinçage coulaire 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

Burn Spray Principal Display Panel SHAKE WELL BEFORE USING

Honeywell BURN SPRAY

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.)

Cat. No. 201005

DRUG FACTS

Active ingredients Purpose Benzethonium chloride 0.2% w/w. Topical antiseptic Benzocaine 10% w/w... Menthol .33% Topical anesthetic 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
 in case of deep or puncture wounds
 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

Inactive ingredients dipropylene glycol, isobutane, n-butane, propane

Questions or comments? 1-800-430-5490



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



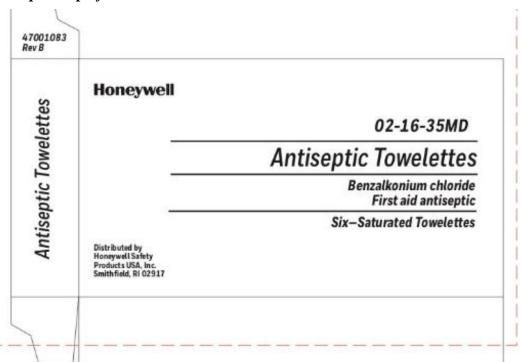
Ammonia

47.0306

Principal Display Panel

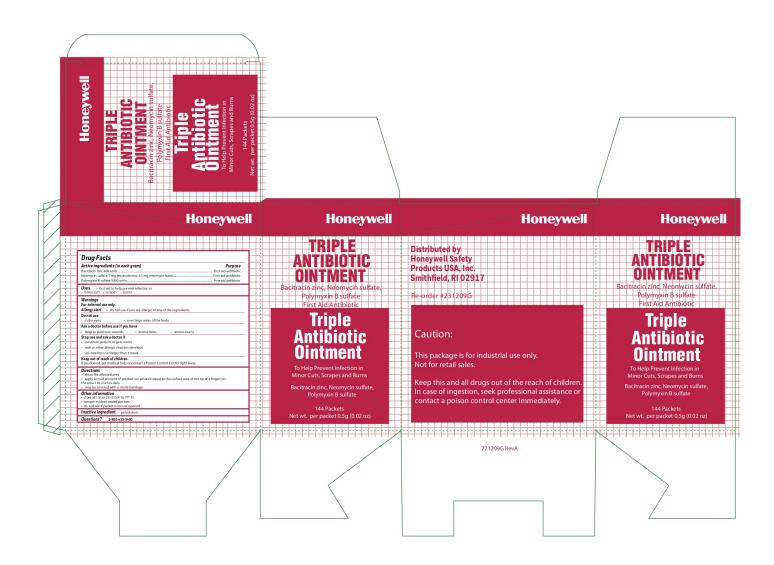
796006 Rev. E (page 3 of 3)

Principal Display Panel

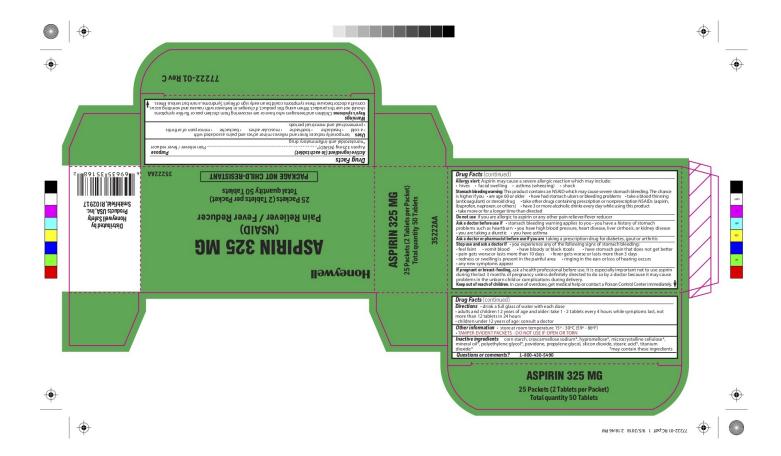


47001083 Rev B	Antiseptic Towelettes	Honeywell
	Drug Facts	\neg
	Active Ingredient Purp a Benzalkonium chloride 0.133% w/v First aid antisept	
	Uses • antiseptic cleaning of face, hands and body without soap and water. • air dries in seconds	
	Warnings For external use only	\neg
	When using this product • do not use in the eyes or apply overlarge areas of the body	
	Ask a doctor before use in case of deep or puncture wounds, animal bites, or serious burns Stop use and consult a doctor if irritation, redness or other symptoms develop condition persists or gets worse	-
	Do not use • longer than I week unless directed by doctor	7
	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away	
	Directions • tear open packet, unfold and use as washcloth	\rightarrow
	Other Information •store at room temperature 15° -30° C(59° -86° F) •do not reuse towelette	
	Inactive ingredient water	
	Questions or comments 1-800-430-5490	-1

Triple Principal Display Panel



As pirin Principal Display Panel



4304 Kit Label SF00004362



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

4304 FIRST AID KIT

4304 first aid kit kit

P	ro	d	u	ct	Inf	01	ma	tion	
---	----	---	---	----	-----	----	----	------	--

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0498-4304

Ш	Packaging					
	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
П	1 NDC:0498-4304-01	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	1 BOTTLE, SPRAY	59 mL		
Part 3	20 PACKET	10 g		
Part 4	10 AMPULE	3 mL		
Part 5	20 PACKET	28 mL		
Part 6	125 PACKET	250		

Part 1 of 6

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)				
SO DIUM PHO SPHATE, DIBASIC (UNII: GR686LBA74)				
SO DIUM PHO SPHATE, MO NO BASIC, MO NO HYDRATE (UNII: 593YOG76RN)				

l	Packaging					
l	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
l	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	12/18/20 18			

Part 2 of 6

BURN RELIEF

lidocaine hydrochloride spray

Product Information

Item Code (Source)	DC:0498-0221
--------------------	--------------

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength LIDO CAINE HYDRO CHLO RIDE (UNII: V13007Z41A) (LIDO CAINE UNII:98 PI200987) LIDO CAINE HYDRO CHLO RIDE ANHYDRO US in 1 mL

Inactive Ingredients			
Ingredient Name	Strength		
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)			
GLYCERIN (UNII: PDC6A3C0OX)			
TROLAMINE (UNII: 9O3K93S3TK)			
PROPYLPARABEN (UNII: Z8 IX2SC1OH)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)			
HYPROMELLOSES (UNII: 3NXW29V3WO)			
TEA TREE OIL (UNII: VIF565UC2G)			
METHYLPARABEN (UNII: A2I8 C7HI9 T)			
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 3 of 6

TRIPLE ANTIBIOTIC

bacitracin zinc, polymyxin b sulfate, neomycin sulfate ointment

Product Information

Item Code (Source) NDC:0498-0750

Route of Administration TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	5000 [iU] in 1 g
BACITRACIN ZINC (UNII: 89 Y4M234ES) (BACITRACIN - UNII:58 H6 RWO 52I)	BACITRACIN	400 [iU] in 1 g
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:116QD7X297)	NEOMYCIN	3.5 mg in 1 g

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

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:0498-0750-36	0.5 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	09/19/2018	

Part 4 of 6

AMMONIA INHALENT

ammonia inhalent inhalant

Product Information

Item Code (Source)	NDC:0498-3334
Route of Administration	RESPIRATORY (INHALATION)

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
AMMO NIA (UNII: 5138 Q19 F1X) (AMMO NIA - UNII:5138 Q19 F1X)	AMMO NIA	0.045 g in 0.3 mL

Inactive Ingredient	s	
	Ingredient Name	Strength
ALCOHOL (UNII: 3K995	8 V9 0 M)	

l	Packaging				
l	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1	NDC:0498-3334-00	0.3 mL in 1 AMPULE; Type 0: Not a Combination Product		

Marketing Information	
ting Start Date Marketing End Date	
18	

Part 5 of 6

ANTISEPTIC TOWELETTE

benzalkonium chloride liquid

Product Information	
Item Code (Source)	NDC:0498-0501
Route of Administration	TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL	

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

l	P	ackaging			
l	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1	NDC:0498-0501-00	1.4 mL 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	part333E	12/21/2017	

Part 6 of 6

ASPIRIN

aspirin tablet

Product Information		
Item Code (Source)	NDC:0498-0114	
Route of Administration	ORAL	

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg

Inactive Ingredients		
Ingredient Name	Strength	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
STARCH, CORN (UNII: O8232NY3SJ)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
CROSCARMELLOSE SODIUM (UNII: M28 OL 1HH48)		
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)		
MINERAL OIL (UNII: T5L8T28FGP)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
PO VIDO NE (UNII: FZ989 GH94E)		
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		

Product Characteristics				
Color	white (white)	Score	2 pieces	
Shape	ROUND	Size	10 mm	
Flavor		Imprint Code	FR21	
Contains				

Pack	aging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC	C:0498-0114-01	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
OTC monograph not final	part343	09/18/2018	

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
James Alexander		040756421	manufacture(0498-3334)

Establishment			
Name	Address	ID/FEI	Business Operations
Honeywell Safety Products USA, INC		079287321	pack(0498-4304)

Establishment				
Name	Address	ID/FEI	Business Operations	
Ultra Seal Corportion		085752004	manufacture(0498-0114)	

Establishment			
Name	Address	ID/FEI	Business Operations
Water-Jel Technologies		155522589	manufacture (0498-0750, 0498-0221)

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Changzhou Maokang Medical		421317073	manufacture(0498-0501)	

Revised: 5/2019 Honeywell Safety Products USA, INC