

4346 FIRST AID KIT- 4346 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.

0498-4346: First Aid Kit (BZK, Miralac, Triple, EW, Pain stopper, Burn Relief-Z68140GRR)

Eyewash
Active ingredient

Sterile Water 99%

Eyewash
Purpose

Eyewash

Eyewash
Uses

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

Eyewash
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.

Eyewash

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

Eyewash**Inactive ingredients**

sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic

Eyewash**Questions**

1-800-430-5490

Triple**Active ingredients**

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

Triple***Inactive ingredient***

petrolatum

Miralac***Active ingredient (in each chewable tablet)*****Miralac*****Purpose***

Antacid

Miralac

Uses

for the relief of

- acid indigestion
- heartburn
- sour stomach
- upset stomach associated with these symptoms

Warnings

Ask a doctor before use if you have

- kidney stones
- calcium-restricted diet

Ask a doctor before use if you are

- presently taking a prescription drug. Antacids may interfere with certain prescription drugs

When using this product

- do not take more than 12 tablets in a 24- hour period, or use the maximum dosage of this product for more than 2 weeks, except under the advice and supervision of a doctor.

Keep out of the reach of children.

In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

Miralac

Directions

- chew 1 to 2 tablets every 4 hours as symptoms occur, or as directed by a doctor.

Miralac

Other information

- each tablet contains: calcium 170 mg
- sucrose free
- lactose free
- store at room temperature
- TAMPER EVIDENT PACKETS- DO NOT USE IF OPEN OR TORN

Miralac

Inactive ingredients

magnesium stearate, mint flavor, silicon dioxide, sorbitol, starch

Miralac***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 ° to 30 ° C (5 ° - 86 ° F)
- do not reuse towelette

BZK

Inactive ingredient

water

BzK

Questions

1-800-430-5490

Questions or Comments?

1-800-430-5490

Pain Stopper

Active ingredient (in each tablet)

Acetaminophen 110mg

Aspirin 162mg (NSAID)*

Caffeine 32.4mg

Salicylamide 152mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Pain Stopper

Purpose

Pain reliever/fever reducer

Pain reliever/fever reducer

Diuretic

Pain reliever/fever reducer

Pain Stopper

Uses

for the temporary relief of minor aches and pains due to:

- common cold
- headache

- muscular aches
- premenstrual and menstrual cramps

Pain Stopper

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

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

- skin reddening
- blisters
- rash

If skin reaction occurs, stop use and seek medical help right away.

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

- more than 12 tablets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

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

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist
- for more than 10 days for pain unless directed by a doctor
- for more than 3 days for fever unless directed by a doctor

Ask a doctor before use if

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

Stop using and ask a doctor if

- symptoms do not improve
- new symptoms occur
- pain or fever persists or gets worse
- 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
- if ringing in the ears or a loss of hearing occurs, consult a doctor before taking any more of this product.

If pregnant or breast-feeding

- ask a healthcare professional before use.

It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during pregnancy.

KEEP OUT OF REACH OF CHILDREN.

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 children even if you do not notice any signs or symptoms.

Pain Stopper

Directions

- adults and children 12 years of age and over, take 2 tablets every 4 hours while symptoms persist
- do not take more than 12 tablets in 24 hours
- children under 12 years: consult a doctor

Pain Stopper

Other information

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

Pain Stopper

Inactive ingredients

FD&C Yellow #6, magnesium stearate, microcrystalline cellulose, povidone, starch, stearic acid,

Pain Stopper
Questions or Comments?

1-800-430-5490

Burn relief WJ
Active ingredient

Lidocaine HCl 2%

Burn Relief WJ
Purpose

External analgesic

Burn Relief WJ
Uses

- temporarily relieves pain due to minor burns

Burn Relief WJ
Warnings

For external use only

Do not use

- over large areas of the body, particularly over raw surfaces or blistered areas

When using this product

- avoid contact with the eyes

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days
- condition clears up and occurs again within a few days

Keep out of the reach of children

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

Burn Relief WJ
Directions

- **adults and children 2 years of age and older:** apply to affected area not more than 3 to 4 times daily
- **children under 2 years of age:** ask a doctor

Burn Relief WJ

Other information

- store at room temperature

Burn Relief WJ

Inactive ingredients

diazolidinyl urea, edetate disodium, glycerin, hypromellose, methylparaben, octoxynol 9, propylene glycol, propylparaben, purified water, tea tree oil, trolamine

Burn Relief WJ

Questions or Comments?

1-800-430-5490



4346

Z68140GRR KIT CONTENTS

1 1X3 PLASTIC 100/BOX
1 WOVEN 7/8 X 3 50/BOX
1 SWIFT KNUCKLE 40/BX
1 SWIFT FINGERTIP 8 50/BOX
2 TRIPLE ANTIBIOTIC 10 PER
1 EYE DRESS PKT W/4 ADH STRIPS
1 INSTANT COLD PACK 4" X 6"
1 ADHESIVE TAPE W/P 1/2"X 5 YD
1 TWEEZER PLASTICS 4"
1 O/H PUMP BURN RELIEF 2 OZ ID G
1 BLOODSTOPPER
1 NON-ADHERENT PADS 2"X3" 10'S
1 GZE PADS STERILE 3"X 3" 25'S
2 ANTISEPTIC WIPES BZK CHL 20'S
1 PAIN STOPPERS IND PK 2ENV 100
1 MIRALAC TABS IND PK 2/ENV 100
1 4OZ BFS EYEWASH TRILINGUAL BOTTLE
1 F A KIT EMPTY BLANK 140
1 POCKET INSERT RED #140 KIT 2R
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
- 1 TRI BNDG NON WOVEN 40"X40"X56"

Eyewash Principal Display Panel

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|  | | | <p>TAMPER-EVIDENT CAP. TAPA CON SELLO DE SEGURIDAD. BOUCHON INDICATEUR D'INFRACTION.</p> | | | | | | | | | | | | | | | | | | | | |
| <p>LAVAOJOS EYESALINE</p> <p>Solución Isotónico Estéril</p> | <p>EYESALINE EYEWASH</p> <p>Sterile Isotonic Solution</p> | <p>LAVAGE OCULAIRE EYESALINE</p> <p>La Solution Isotonique Stérile</p> | <p>NPN: 80057528</p>  <p>64809 11 45033 17</p> | <p>Drug Facts (for USA only)</p> <table border="1"> <tr> <td>Active ingredient Sterile water 99%</td> <td>Purpose Eyewash</td> </tr> <tr> <td colspan="2">Uses for flushing the eye to remove loose foreign material, air pollutants, or chlorinated water.</td> </tr> <tr> <td colspan="2">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.</td> </tr> <tr> <td colspan="2">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</td> </tr> <tr> <td colspan="2">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</td> </tr> <tr> <td colspan="2">Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</td> </tr> <tr> <td colspan="2">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</td> </tr> <tr> <td colspan="2">Inactive ingredients sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic</td> </tr> <tr> <td colspan="2">Questions? Call 1-800-430-5490 Honeywell Safety Products USA, Inc. Smithfield, RI. 02917</td> </tr> </table> | | 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 | |
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| <p>16 fl. oz. (473 mL)</p> | | | <p>space for lot code and supplier part number</p> <p>PEEL / PELAR / PELER</p> | | | | | | | | | | | | | | | | | | | | |

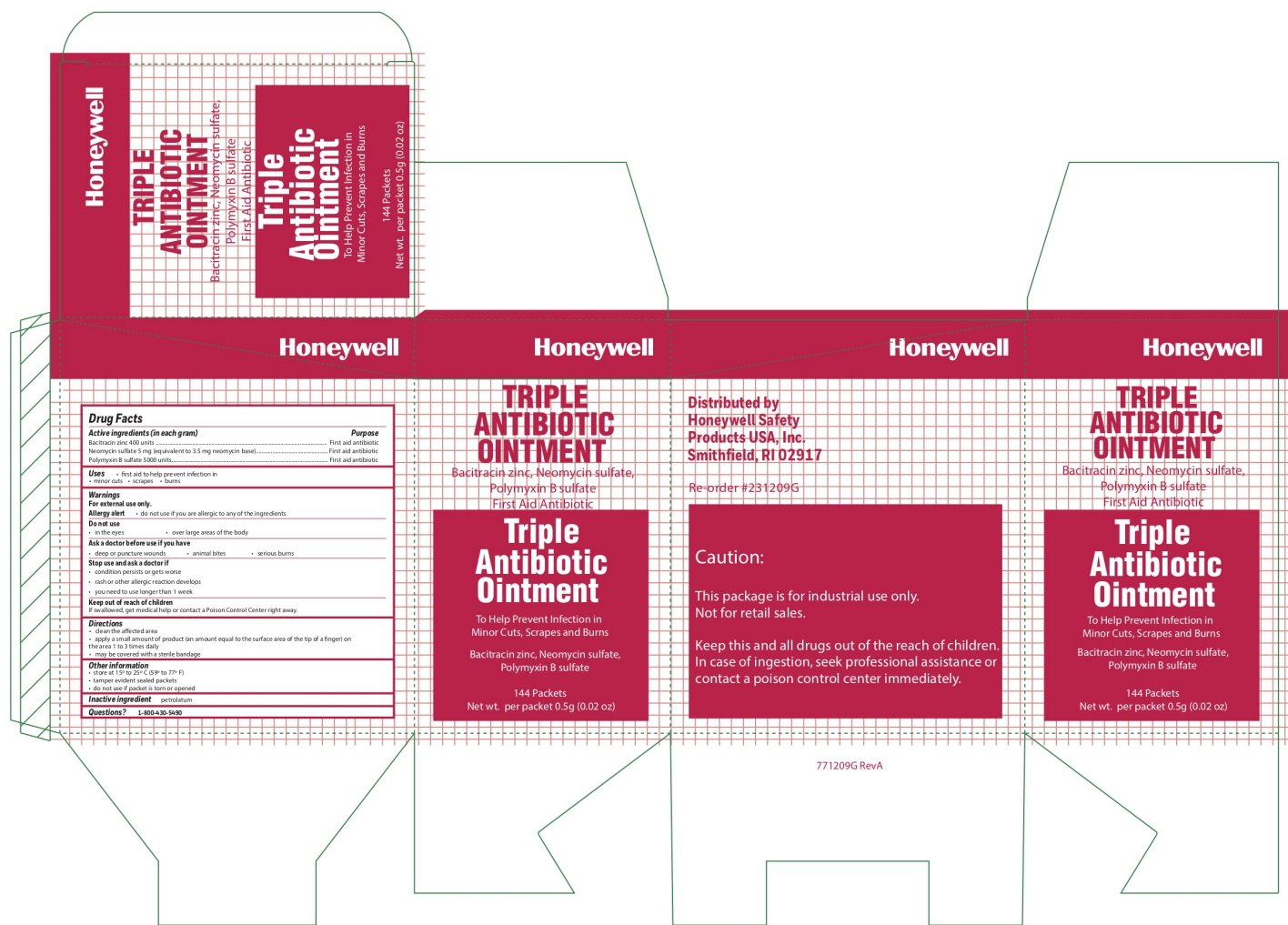
Datos de medicamento (Para EE.UU. solamente)

| | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|
| Ingrediente Activo Agua estéril 99% | Propósito Lavajos |
| 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 enjuagando con un lavajos 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 sentez 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 |

Triple
Principal Display Panel



Miralac
Principal Display Panel

47001083
Rev B

Antiseptic Towelettes

Honeywell

02-16-35MD

Antiseptic Towelettes

Benzalkonium chloride
First aid antiseptic

Six-Saturated Towelettes

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

Antiseptic Towelettes

Honeywell

47001083
Rev B

Drug Facts

Active Ingredient

Benzalkonium chloride 0.133% w/v

Purpose

First aid antiseptic

Uses

- antiseptic cleaning of face, hands and body without soap and water.
- air dries in seconds

Warnings

For external use only

When using this product • do not use in the eyes or apply over large 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 1 week unless directed by doctor

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

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

Pain Stopper
Principal Display Panel



032204 Rev. H North Burn Relief Spray
Two Color: Red PMS 032 & Black

032204



**BURN RELIEF
SPRAY**

Lidocaine HCl
External analgesic

2 FL OZ (59 mL)

Package Not Child Resistant

ANSI Z308.1-2003


8 21812 01499 9

Drug Facts

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| Active ingredient Lidocaine HCl 2%..... | Purpose External analgesic |
| Use temporarily relieves pain due to minor burns | |
| Warnings | |
| For external use only | |
| Do not use over large areas of the body, particularly over raw surfaces or blistered areas | |
| When using this product avoid contact with the eyes | |
| Stop use and ask a doctor if • condition worsens • symptoms last more than 7 days • condition clears up and occurs again within a few days | |
| Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. | |
| Directions | |
| • adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily | |
| • children under 2 years of age: ask a doctor | |
| Other information store at room temperature | |
| Inactive ingredients diazolidinyl urea, edetate disodium, glycerin, hypromellose, methylparaben, octoxynol 9, propylene glycol, propylparaben, purified water, tea tree oil, trolamine | |
| Questions or comments? 1-800-430-5490 | |

Mfg. for: Honeywell Safety Products USA, Inc. Smithfield, RI 02917 032204 Rev. H



032204K Rev. F (Page 3 of 3)



4346 Kit Label
Z68140GRR



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

4346 FIRST AID KIT

4346 first aid kit kit

Product Information

| | | | |
|--------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0498-4346 |
|--------------|----------------|--------------------|---------------|

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|-----------------------------------------------|----------------------|--------------------|
| 1 | NDC:0498-4346-01 | 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 | 18 g |
| Part 4 | 50 PACKET | 100 |
| Part 5 | 40 PACKET | 56 mL |
| Part 6 | 50 PACKET | 100 |

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

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 6 | | | | |
| 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 | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | | | | |
| DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4) | | | | |
| TROLAMINE (UNII: 9O3K93S3TK) | | | | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | | | | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | | | | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | | | | |
| OCTOXYNOL-9 (UNII: 7JPC6Y25QS) | | | | |
| WATER (UNII: 059QF0KO0R) | | | | |
| TEA TREE OIL (UNII: VIF565UC2G) | | | | |
| | | | | |
| 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 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: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I) | BACITRACIN | 400 [iU] in 1 g |
| NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297) | 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:0498-0750-35 | 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 |
|--------------------------|------------------------------------------|----------------------|--------------------|
| unapproved drug other | | 09/19/2018 | |

Part 4 of 6

MIRALAC

calcium carbonate tablet

Product Information

Item Code (Source) NDC:0498-0303

Route of Administration ORAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------------------------------------------------------------------------------------------------------|-------------------|----------|
| CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB, CARBONATE ION - UNII:7UJQ5OPE7D) | CALCIUM CARBONATE | 420 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| SORBITOL (UNII: 506T60A25R) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|----------|
| Color | white | Score | 2 pieces |
| Shape | ROUND | Size | 11mm |
| Flavor | MINT | Imprint Code | FR8 |
| 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 | | 02/22/2012 | |

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 |
|-----------------------------------------------------------------------------------|-----------------------|----------------|
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | 1.3 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------|----------|
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|-------------------------------------------------------|----------------------|--------------------|
| 1 | NDC:0498-0501-00 | 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 |
|--------------------------|------------------------------------------|----------------------|--------------------|
| unapproved drug other | | 12/22/2017 | |

Part 6 of 6

PAIN STOPPERS

acetaminophen, caffeine, aspirin, salicylamide tablet

Product Information

Item Code (Source) NDC:0498-2422

Route of Administration ORAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---------------------------------------------------------------------------|-------------------|----------|
| CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E) | CAFFEINE | 32.4 mg |
| SALICYLAMIDE (UNII: EM8BM710ZC) (SALICYLAMIDE - UNII:EM8BM710ZC) | SALICYLAMIDE | 152 mg |
| ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) | ASPIRIN | 162 mg |
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 110 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|-------------------------------------------------------|----------|
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| POVIDONE K30 (UNII: U725QWY32X) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |

Product Characteristics

| | | | |
|-----------------|------------------------|---------------------|----------|
| Color | orange (BRIGHT ORANGE) | Score | no score |
| Shape | ROUND | Size | 11mm |
| Flavor | | Imprint Code | FR;2 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--------------------------------------------------|----------------------|--------------------|
| 1 | NDC:0498-2422-01 | 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 |
|--------------------------|------------------------------------------|----------------------|--------------------|
| unapproved drug other | | 01/02/2017 | |

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 (118768815)

