

4395 FIRST AID KIT - 4395 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](#).

4395 First Aid Kit (BZK wipe, FABC, neomycin, alcohol wipes, ASA, aypanal, cedaprin-Z019840)

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 15⁰ to 25⁰ C (59⁰ to 77⁰F)

Alcohol Wipe

Inactive ingredient

water

Alcohol Wipe

Questions

1-800-430-5490

Aspirin

Active ingredient (in each tablet)

Aspirin 325 mg (NSAID)* *nonsteroidal anti-inflammatory drug

Aspirin

Purpose

Pain reliever/fever reducer

Aspirin

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

Aspirin

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 breast-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 hours

- children under 12 years of age: consult a doctor

Aspirin

Other information

- store at room temperature 15° - 30°C (59° - 86°F)
- TAMPER EVIDENT 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 dioxide*

*may contain these ingredients

Aspirin

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 15⁰ to 30⁰ C (59⁰ - 86⁰ F)
- do not reuse towelette

BZK***Inactive ingredient***

water

BZK***Questions***

1-800-430-5490

Neomycin***Active ingredient (each gram contains)***

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

Ask a doctor before use if you have

- 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 reach of children

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

Neomycin

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

Neomycin

Other information

- store at 15⁰ to 25⁰ C (59⁰ to 77⁰ F)

Neomycin

Inactive ingredient

petrolatum

Neomycin

Questions

1-800-430-5490

Aypanal EX

Active ingredient

Acetaminophen 500 mg

Aypanal EX

Purpose

Pain reliever/fever reducer

Aypanal EX

Uses

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

Aypanal EX

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.
- 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 skin reaction 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 use and ask a doctor if

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present
- If pregnant or breastfeeding,
- ask a health professional before use.

Keep out of reach of children.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Aypanal EX

Directions

- **do not take more than directed (see overdose warning)**
- adults and children 12 years of age and over: Take 2 tablets with water every 6 hours while symptoms last.
- do not take any more than 8 tablets in 24 hours.
- children under 12: consult a doctor

Aypanal EX

Other information

- store at room temperature 15⁰ -30⁰ C (59⁰ -86⁰ F)
- TAMPER EVIDENT- DO NOT USE IF OPEN OR TORN

Aypanal EX

Inactive ingredients

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

Aypanal EX***Questions or Comments?***

1-800-430-5490

FABC***Active ingredient***

Benzalkonium chloride 0.13%

Lidocaine HCl 0.5%

FABC***Purpose***

First Aid antiseptic

External analgesic

FABC***Uses***

- prevent skin infection
- for temporary relief of pain associated with minor burns

FABC***Warnings***

For external use only

Do not use

- in or near the eyes
- if you are allergic to any of the ingredients
- in large areas of the body, particularly over raw surfaces or blistered areas
- for more than 10 days

Ask a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burns

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days or clear 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.

FABC***Directions***

- **adults and children 2 years of age and older:**
- clean the affected area
- apply a small amount of this product (equal to the surface area of the tip of a finger) onto affected area 1 to 3 times daily
- may be covered with a sterile bandage
- **children under 2 years of age: consult a doctor**

FABC

Other information

- tamper evident sealed packets
- do not use if packet is opened or torn

FABC

Inactive ingredients

aloe barbadensis juice, cetyl alcohol, diazolidinyl urea, edetate disodium, glycerin, glyceryl stearate SE, methylparaben, mineral oil, PEG-100, propylene glycol, propylparaben, stearic acid, trolamine, water

FABC

Questions

1-800-430-5490

Cedaprin

Active ingredient

Ibuprofen 200 mg (NSAID)

*(nonsteroidal anti-inflammatory drug)

Cedaprin

Purpose

Pain reliever/fever reducer

Cedaprin

Uses

temporarily relieves minor aches and pains due to:

- headache
- muscular aches
- minor pain of arthritis
- toothache
- backache
- the common cold
- menstrual cramps
- temporarily reduces fever

Cedaprin

Warnings

Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin.

Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

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

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

Heart attack and stroke warning:

- NSAID's, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to ibuprofen or any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- you have problems or serious side effects from taking pain relievers or fever reducers
- 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, kidney disease, asthma or had a stroke
- you are taking a diuretic

Ask a doctor or a pharmacist before use if you are

- taking aspirin for heart attack or stroke, because ibuprofen may decrease the benefit of aspirin
- under a doctor's care for any serious condition
- taking any other drug

When using this product,

take with food or milk if stomach upset occurs

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
- you have symptoms of heart problems or stroke:
- chest pain
- trouble breathing
- weakness in one part or side of body
- slurred speech
- leg swelling
- 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
- any new symptoms appear

If pregnant or breast-feeding,

ask a health professional before use. It is especially important not to use ibuprofen 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 delivery.

Keep out of reach of children.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away(1-800-222-1222). Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms..

Cedaprin

Directions

- do not take more than directed
- the smallest effective dose should be used
- adult and children 12 years of age and over:
- take 1 tablet every 4 to 6 hours while symptoms persist
- if pain or fever does not respond to 1 tablet, 2 tablets may be used
- do not exceed 6 tablets in 24 hours, unless directed by a doctor
- children under 12 years: ask a doctor

Cedaprin

Other information

- store between 15⁰ -30⁰ C (59⁰ -86⁰ F)
- avoid excessive heat and humidity
- TAMPER EVIDENT PACKETS- DO NOT USE IF OPEN OR TORN

Cedaprin

Inactive ingredients

hypromellose, lactose monohydrate, opadry II 31K, povidone K-30, ferric oxide red, silicon dioxide, starch, stearic acid, titanium dioxide, triacetin

Cedaprin

Questions or Comments?

1-800-430-5490

4395

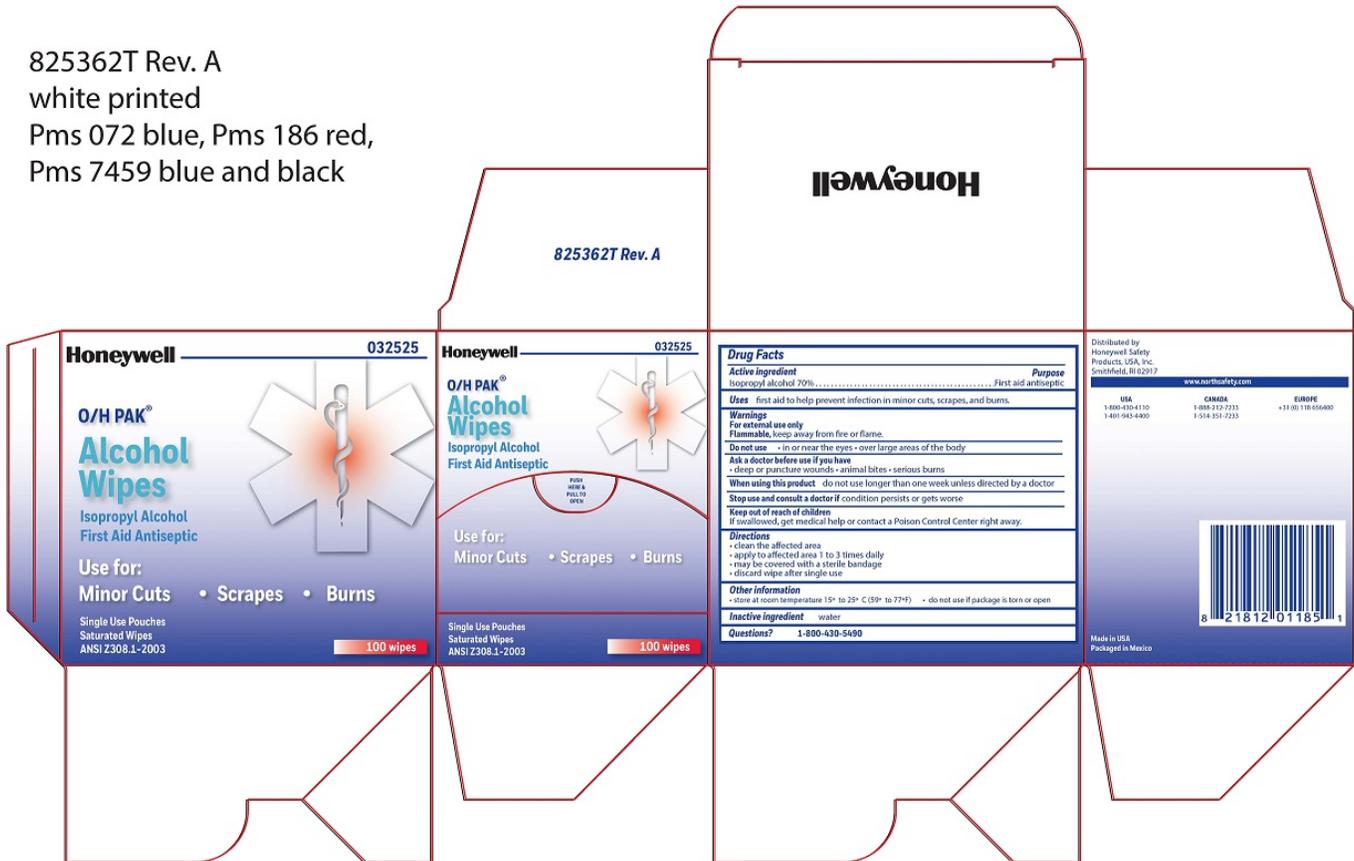
Z019840 KIT CONTENTS

1 XTRA LRG 2" X 4" AWC
1 ADHESIVE TAPE W/P 1/2"X 5 YD
1 TWEEZER PLASTICS 4"
1 FIRST AID GUIDE ASHI
1 EMERGENCY SURVIVAL BLANKET
1 ABD COMBINE PAD 5" X 9"
10 CTA 3" SINGLE TIP
1 TONGUE BLADES SR WRAPPED
LBL STOCK 6-3/8"X4"
LBL STOCK 4"X2-7/8"
1 LBL STOCK 3"x1-7/8"
1 LBL CONTS 8"X8",CUSTOM ID B
12 BZK ANTISEPTIC WIPE, BULK
1 SOFT PACK, CLOTH BAG- MEDIUM
1 PR LRG NITRILE GLVES ZIP BAG
1 FIRST AID CREAM 1.0GR PKT EACH
1 SWIFT 3/4" X 3" PLAS 50 ZIPBAG
4 POUCH NEOMYCIN ANTIBIOTIC .9 G
5 ADH BANDAGE BUTTERFLY 1980000
8 WIPE ALCOHOL PREP IPA 70% (DUKAL)
20 ADH BANDAGE 3/8" X 1 1/2" DNX
1 COLD PACK UNIT 4"X6" BULK
5 GAUZE PADS 2"X2" 12PLY
1 EYE PADS STD OVAL STERILE
1 GAUZE PADS 3"X3" 12PLY
12 PLASTIC SPOT 7/8" DIAM DNX
20 PLASTIC BANDAGE 1" X 3"
8 WOVEN FINGERTIP BANDAGE 2"
8 WOVEN KNUCKLE BANDAGE
10 WOVEN BANDAGE 1" X 3"
1 ZIP LOCK 2 X 4" 2ML
1 ASPIRIN BULK 2/PK
2 AYPANAL EXTRA BULK 2/PK

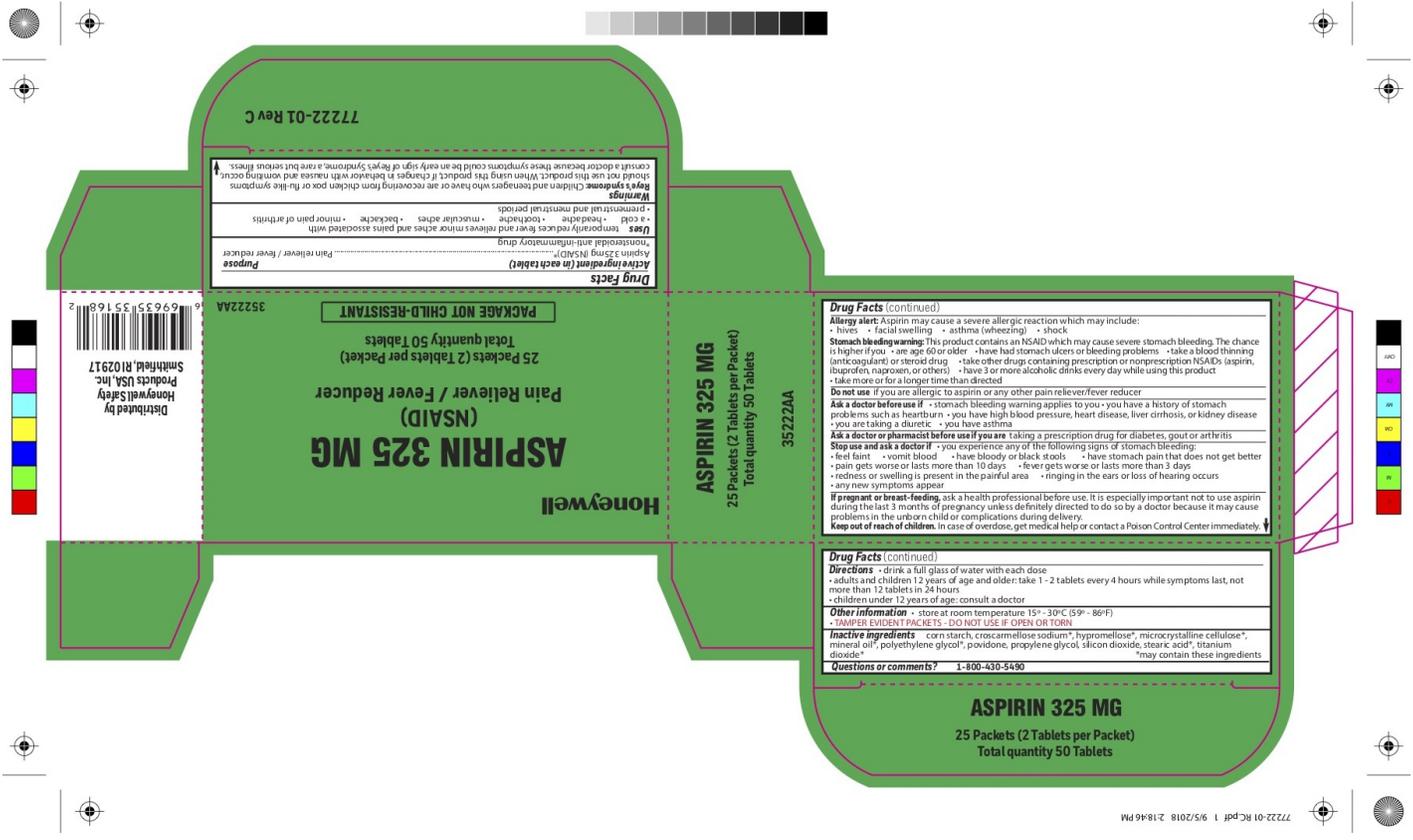
1 CEDAPRIN BULK 2/PK

Alcohol Wipe Label

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



Aspirin
 Principal Display Panel



7722-01 Rev C

Drug Facts (continued)
Active ingredient (in each tablet): Aspirin 325mg (NSAID)
Purpose: Pain reliever / fever reducer
Nonsteroidal anti-inflammatory drug
Uses: temporarily reduces fever and relieves minor aches and pains associated with:
 - cold - headache - toothache - menstrual cramps - muscle aches - backache - minor pain of arthritis
Warnings:
 - aspirin allergy: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, 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.
Warnings (continued):
 - aspirin allergy: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, 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.

PACKAGE NOT CHILD-RESISTANT
 Total quantity 50 Tablets
 25 Packets (2 Tablets per Packet)
Pain Reliever / Fever Reducer
ASPIRIN 325 MG
(NSAID)
Honeywell
 35222AA
 6 96351 53168 2
 Distributed by
 Honeywell Safety
 Products, USA, Inc.
 Smithfield, RI 02917

ASPIRIN 325 MG
 25 Packets (2 Tablets per Packet)
 Total quantity 50 Tablets
 35222AA

Drug Facts (continued)
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, ask a health 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 delivery.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center immediately.

Drug Facts (continued)
Directions - drink a full glass of water with each dose
 • adults and children 12 years of age and older: take 1 - 2 tablets every 4 hours while symptoms last, not more than 12 tablets in 24 hours
 • children under 12 years of age: consult a doctor
Other information - Store at room temperature 15° - 30° C (59° - 86° F)
 • **KEEP OPEN PACKETS DO NOT USE IF OPEN OR TORN**
Inactive ingredients - corn starch, croscarmellose sodium, hypromellose, microcrystalline cellulose, mineral oil, polyethylene glycol, povidone, propylene glycol, silicon dioxide, stearic acid, titanium dioxide
 *may contain these ingredients
Questions or comments? 1-800-430-5490

ASPIRIN 325 MG
 25 Packets (2 Tablets per Packet)
 Total quantity 50 Tablets

7722-01 Rev C.pdf 1 9/5/2018 2:18:46 PM

BZK
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

47001083
Rev B

Antiseptic Towelettes

Honeywell

Drug Facts

Active Ingredient	Purpose
Benzalkonium chloride 0.133% w/v	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

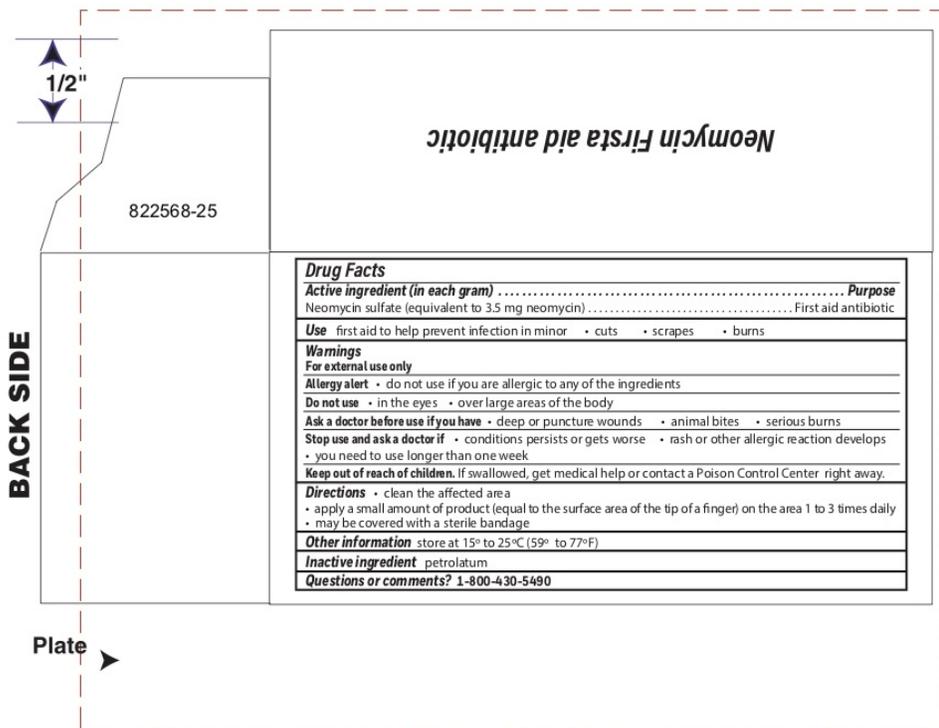
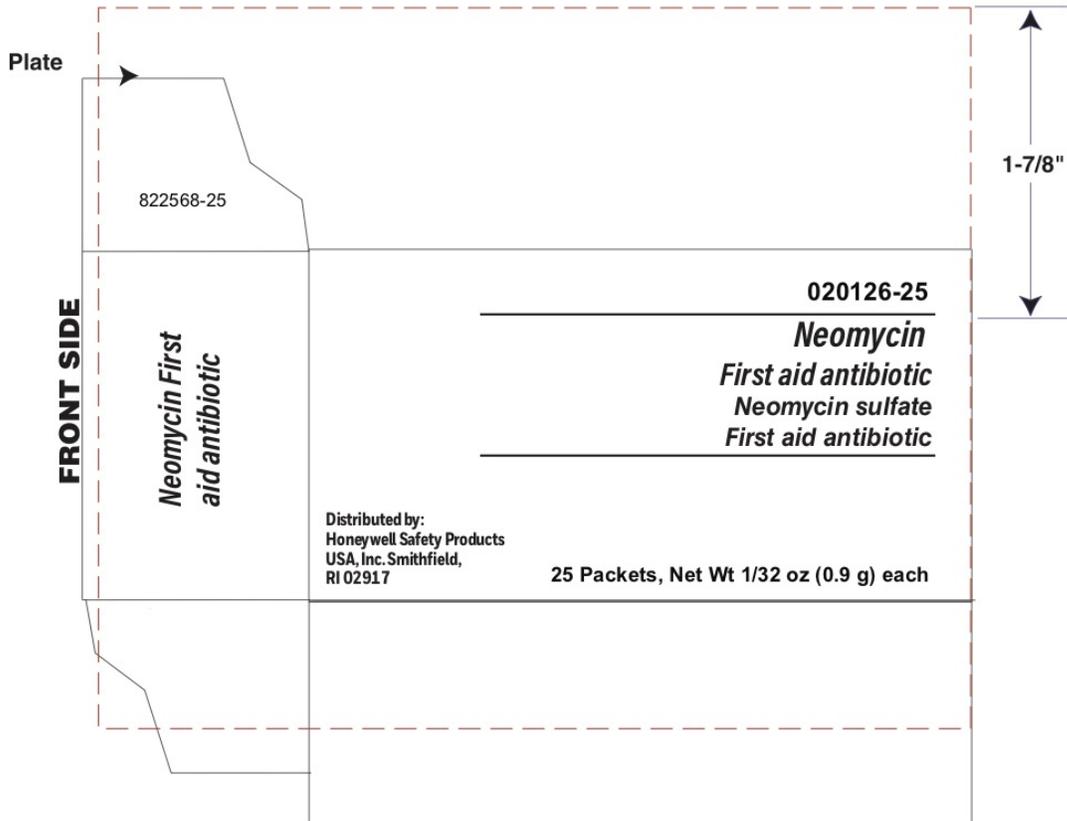
• store at room temperature 15° -30° C (59° -86° F) • do not reuse towelette

Inactive ingredient water

Questions or comments 1-800-430-5490

Neomycin
Principal Display Panel

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



901850-10

First Aid Burn Cream

021020-10

First Aid Burn Cream
Benzalkonium chloride
First aid antiseptic
Lidocaine HCl
External analgesic

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

10 Packets, Net Wt 1/32 oz (0.9g) each

901850-10

First Aid Burn Cream

Drug Facts	
Active ingredients Benzalkonium chloride 0.13% Lidocaine HCl 0.5%	Purposes First aid antiseptic External analgesic
Use - prevent skin infection - for the temporary relief of pain associated with minor burns	
Warnings For external use only	
Do not use - in or near the eyes - if you are allergic to any of the ingredients - in large areas of the body particularly over raw surfaces or blistered areas - for more than 10 days	
Ask a doctor before use if you have - deep or puncture wounds - animal bites - serious burns	
Stop use and ask a doctor if - condition worsens - symptoms persist more than 7 days or clear up and occur 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 and over: - clean the affected area - apply a small amount of this product (equal to the surface area of the tip of a finger) onto affected area 1 to 2 times daily - may be covered with a sterile bandage	
children under 2 years: ask a doctor	
Other information - tamper evident sealed packets - do not use if packet is opened or torn	
Inactive ingredients aloe barbadensis leaf juice, cetyl alcohol, diazolidinyl urea, edetate disodium, glycerin, glyceryl stearate SE, methylparaben, mineral oil, PEG-100, propylene glycol, propylparaben, stearic acid, triethylamine, water	
Questions or comments? 1-800-430-5430	

Cedaprin
Principal Display Panel

46001404 Rev. C
prints 2 colors black and red (pms 485)

Refill Information

US Poison Control 1-800-222-1222

46001404 Rev. C

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

4395 first aid kit kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0498-4395
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4395-01	1 in 1 KIT; Type 0: Not a Combination Product	10/18/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	8 POUCH	3.2 mL
Part 2	1 PACKET	2
Part 3	4 PACKET	3.6 g
Part 4	12 PACKET	16.8 mL
Part 5	2 PACKET	4
Part 6	1 PACKET	0.9 g
Part 7	1 PACKET	2

Part 1 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
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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
OTC mono graph not final	part333A	09/18/2018	

Part 2 of 7

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
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
MINERAL OIL (UNII: T5L8T28FGP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Product Characteristics

Color	white	Score	2 pieces
Shape	ROUND	Size	10mm
Flavor		Imprint Code	FR21
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC: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	

Part 3 of 7

NEOMYCIN

antibiotic ointment

Product Information

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

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0730-01	0.9 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	03/31/2010	

Part 4 of 7

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
OTC monograph not final	part333E	12/22/2017	

Part 5 of 7**AYPANAL EX**

acetaminophen tablet

Product Information**Item Code (Source)** NDC:0498-2110**Route of Administration** ORAL**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients

Ingredient Name	Strength
POVIDONE (UNII: FZ989GH94E)	

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	FR1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-2110-01	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	01/02/2017	

Part 6 of 7

FIRST AID BURN

benzalkonium chloride, lidocaine hydrochloride cream

Product Information

Item Code (Source)	NDC:0498-0903
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 g
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE	0.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

CETYL ALCOHOL (UNII: 936JST6JCN)	
PEG-100 STEARATE (UNII: YD01N1999R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.9 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part333A	12/20/2017	

Part 7 of 7

CEDAPRIN

ibuprofen tablet

Product Information

Item Code (Source)	NDC:0498-7502
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TRIACETIN (UNII: XHX3C3X673)	
POVIDONE K30 (UNII: U725QWY32X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	red	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	G;2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-7502-01	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
ANDA	ANDA079129	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 (079287321)

Establishment

Name	Address	ID/FEI	Business Operations
Honeywell Safety Products USA, INC		079287321	pack(0498-4395)

Establishment

Name	Address	ID/FEI	Business Operations
Ultra Seal Corporation		085752004	manufacture(0498-0114, 0498-2110)

Establishment

Name	Address	ID/FEI	Business Operations
Water-Jel Technologies		155522589	manufacture(0498-0730, 0498-0903)

Establishment

Name	Address	ID/FEI	Business Operations
Changzhou Maokang Medical		421317073	manufacture(0498-0143, 0498-0501)

Establishment

Name	Address	ID/FEI	Business Operations
Granules of India Limited		918609236	manufacture(0498-7502)

Revised: 8/2019

Honeywell Safety Products USA, INC