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.

0498-4395: 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 15 ^{0} to 25 ^{0} C (59 ^{0} to 77 ^{0}F)

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 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 hours
- 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 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 15 ^{0} to 30 ^{0} C (59 ^{0} - 86 ^{0} 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 15 ^{0} to 25 ^{0} C (59 ^{0} to 77 ^{0} 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 ofl 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 15 ^{0} -30 ^{0} C (59 ^{0} -86 ^{0} 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
- lin 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
Direcctions

- **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 effectsfrom 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 doctors 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 oe 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 15 ^{0} -30 ^{0} C (59 ^{0} -86 ^{0} 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

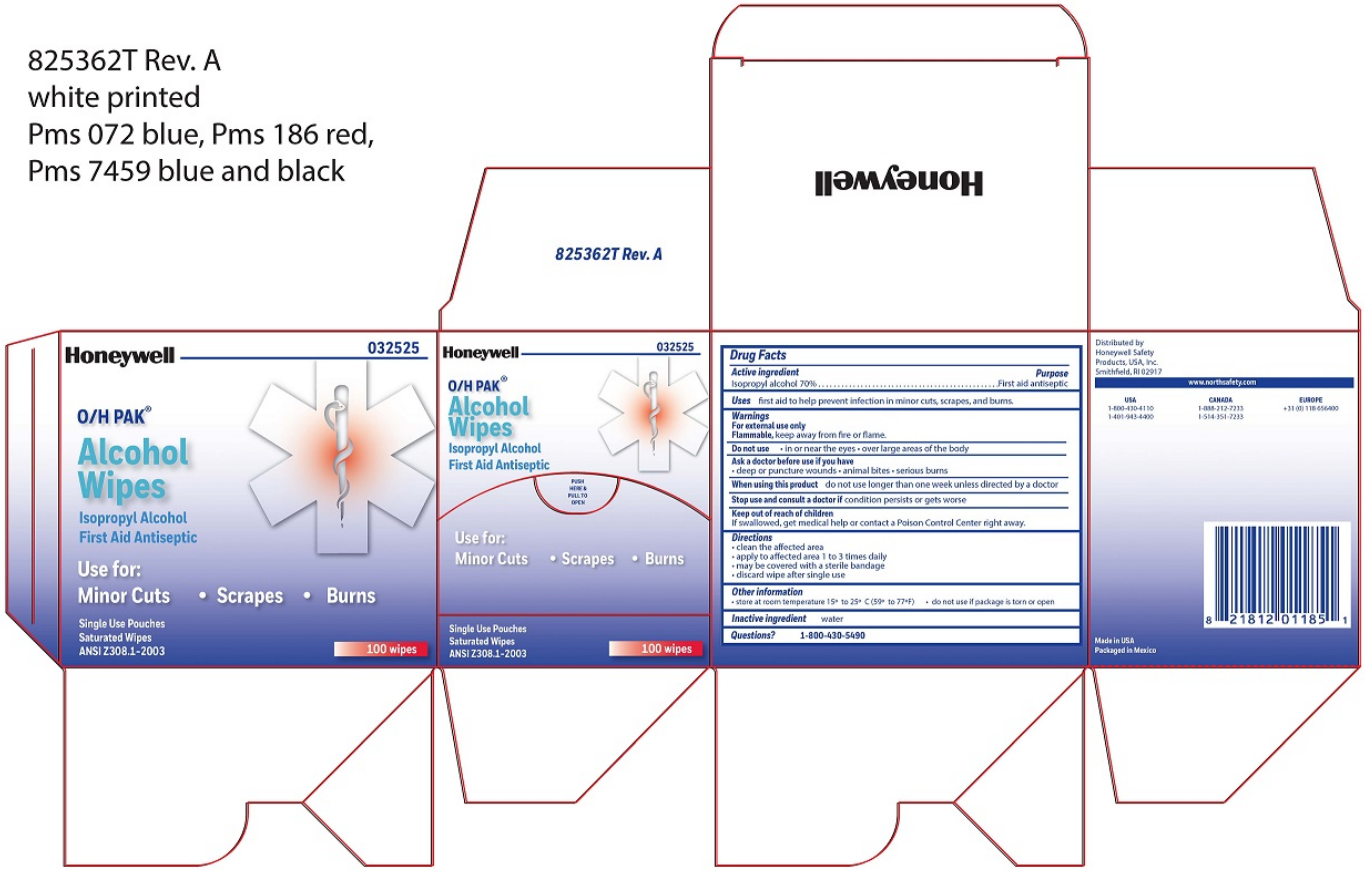
1 ASPIRIN BULK 2/PK

2 AYPANAL EXTRA BULK 2/PK

1 CEDAPRIN BULK 2/PK

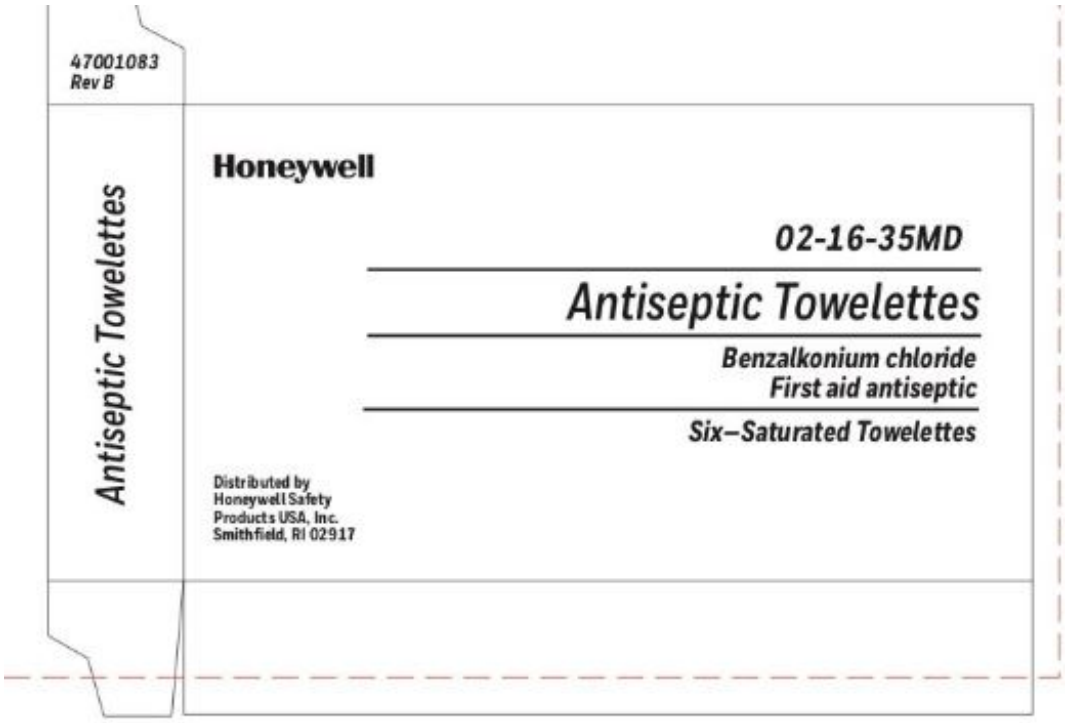
Alcohol Wipe Label

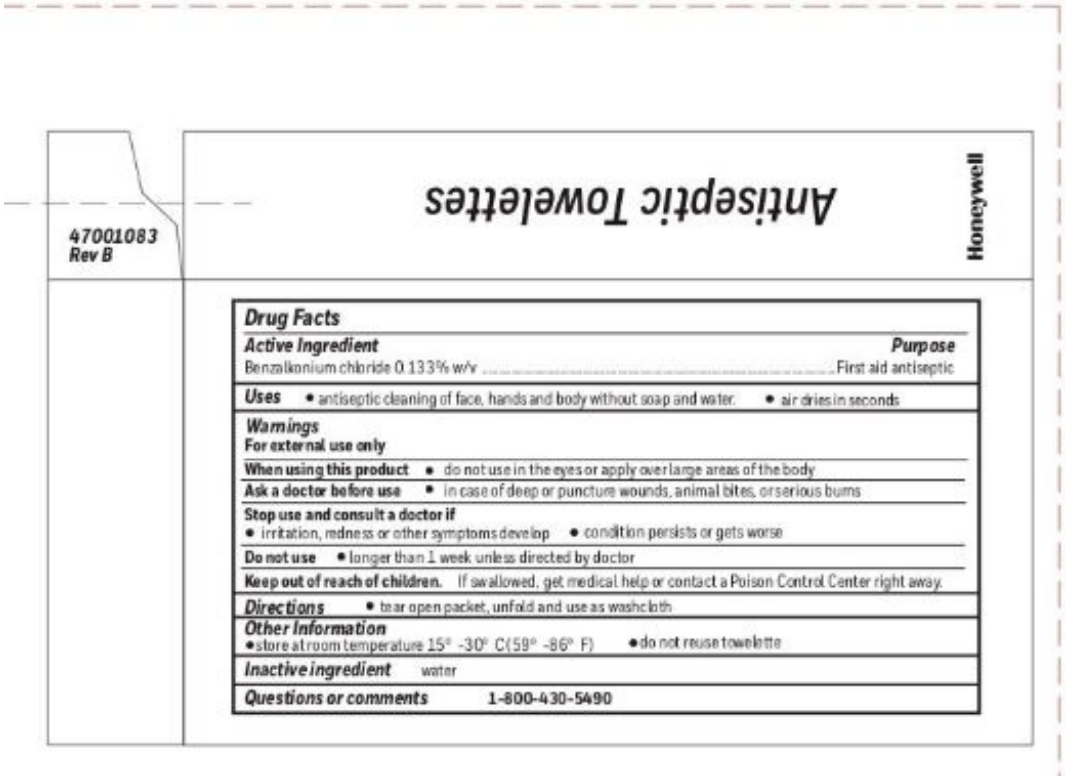
825362T Rev. A
white printed
Pms 072 blue, Pms 186 red,
Pms 7459 blue and black



Aspirin
Principal Display Panel

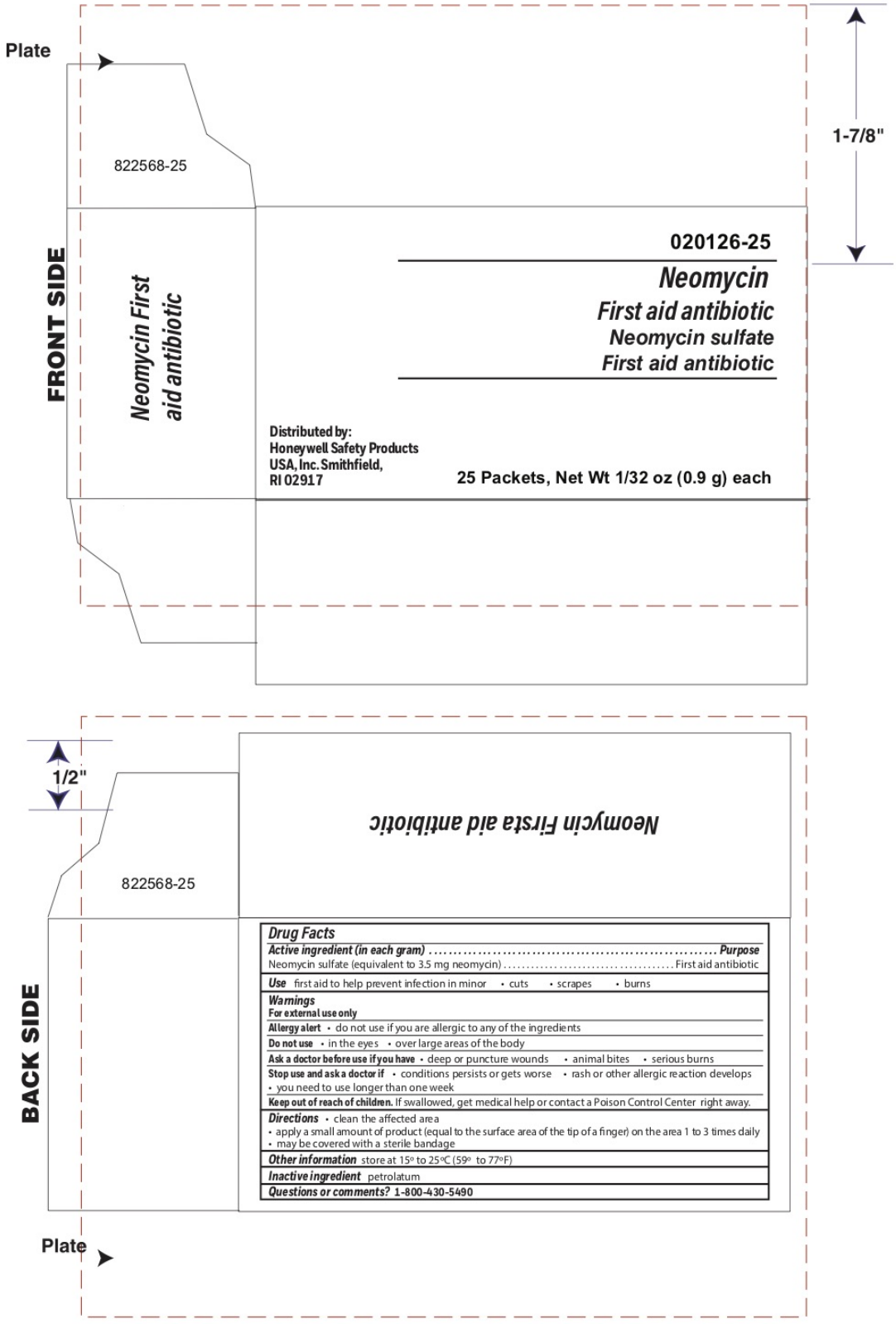
BZK
Principal Display Panel





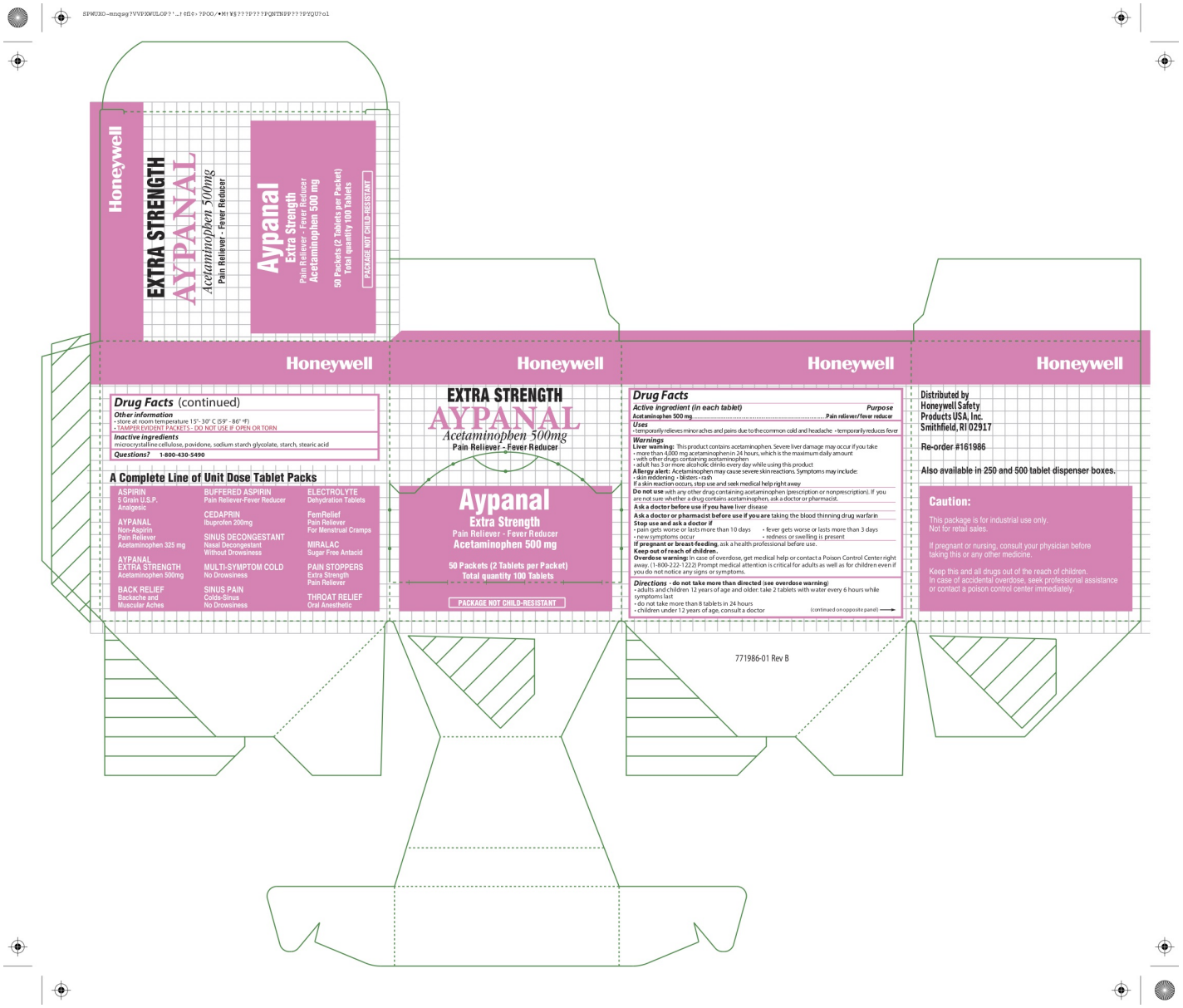
Neomycin
Principal Display Panel

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



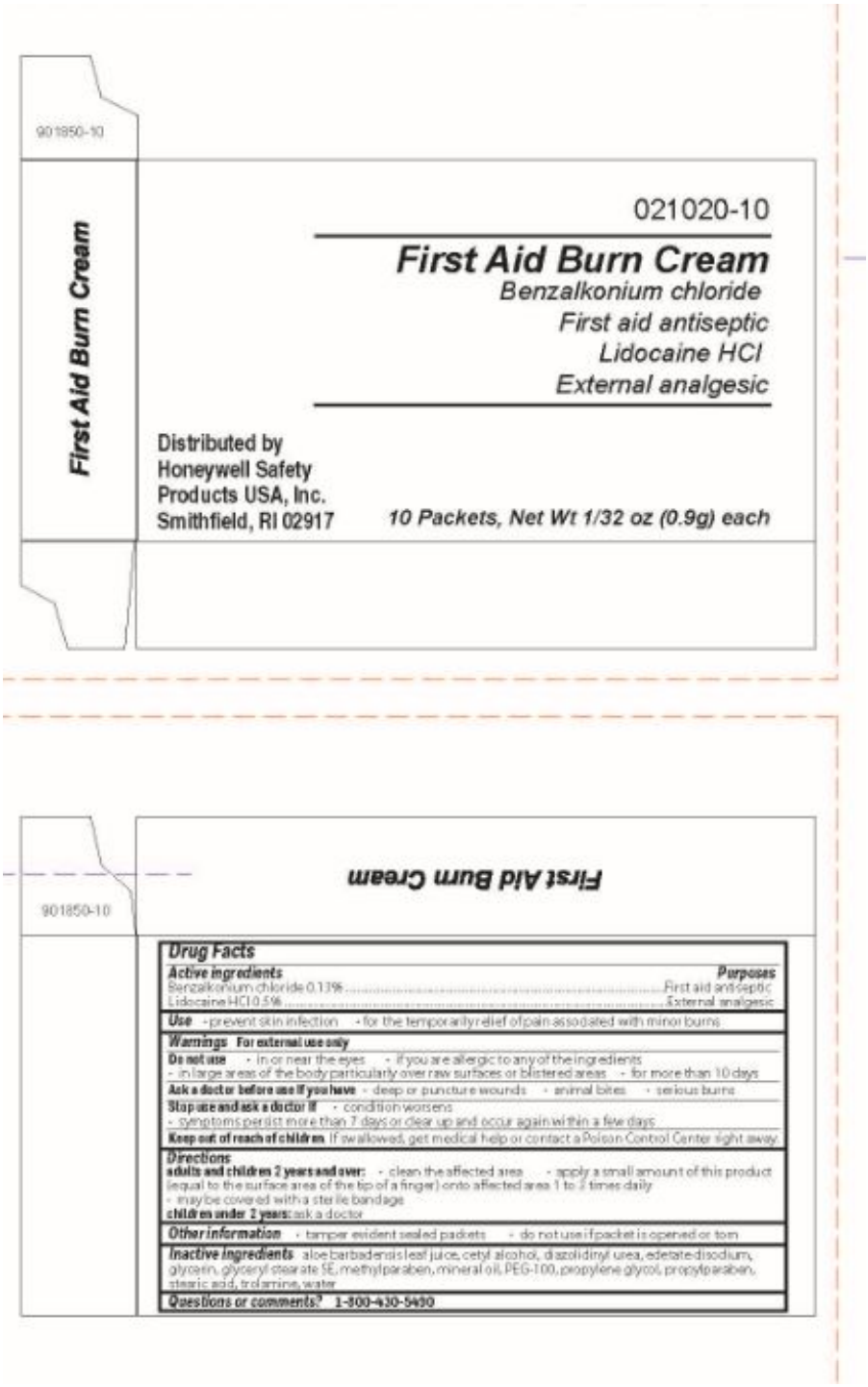
Aypanal EX

Principal Display Panel

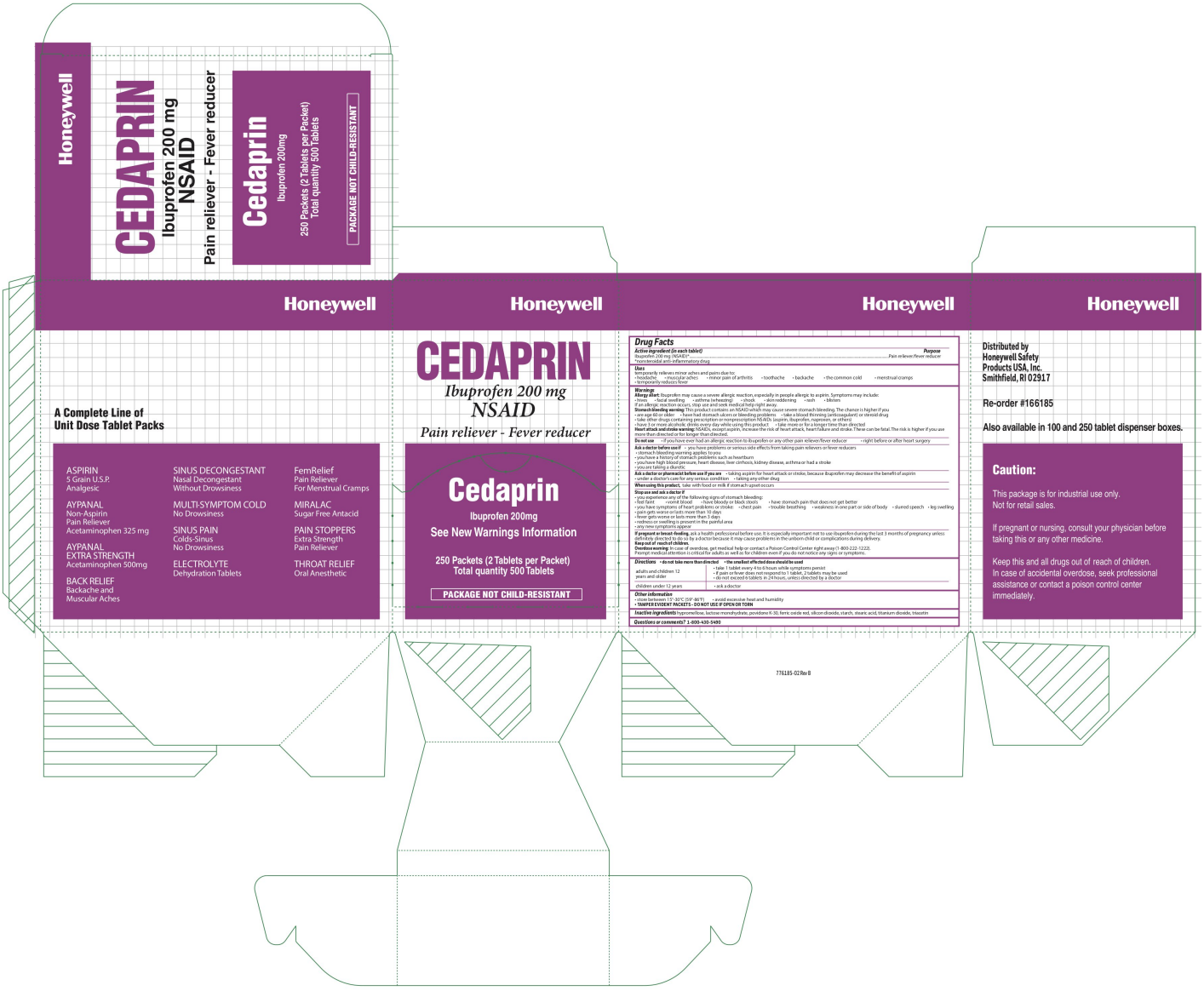


FABC

Principal Display Panel



Cedaprin
Principal Display Panel



4395 Kit Label
Z019840

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

4395 first aid kit kit

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

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
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 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: 3WQ0SDW1A)	
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
unapproved drug other		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
unapproved drug other		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
unapproved drug other		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**
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POVIDONE (UNII: FZ989GH94E)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

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
unapproved drug other		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
unapproved drug other		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: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	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 (118768815)

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