4379 FIRST AID KIT- 4379 first aid kit
4334 FIRST AID KIT- 4334 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.

0498-4334 & 0498-4379: First Aid Kit (triple, Burn Jel, alcohol wipe, PVP wipe, BZK, sting relief, Foille, aypanal EX- Z019819, Z63158006)

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 ^{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

Alcohol
Active ingredient

Isopropyl alcohol 70%

Alcohol
Purpose

First aid antiseptic

Alcohol
Uses

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

Alcohol
Warnings

For external use only

Flammable, keep away from fire or flame.

Do not use
- in the eyes
- over large areas of the body

Ask a doctor before use if you have

deep or puncture wounds

animal bites

serious burns

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
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
Other information

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

Alcohol
Inactive ingredient

water

Foille
Active ingredient

Benzocaine 5.0% (w/w)

Chloroxylenol 0.1% (w/w)

Foille
Purpose

External analgesic

Antiseptic

Foille
Uses

- For the temporary relief of pain associated with burns, sunburn, minor cuts, scrapes, insect bites, and minor skin irritations.
- First aid to help prevent infection in minor cuts, scrapes and burns.

Foille
Warnings

For external use only

When using this product

- avoid contact with the eyes

Stop use and ask a doctor if

- condition worsens, or symptoms persist for more than 7 days or clear up and occur again within a few days.
- Do not apply over large areas of the body. In case of deep or puncture wounds, animal bites, or serious burns, consult a doctor.

Keep out of reach of children.

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

Foille
Directions

- clean the affected area.
- 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: consult a physician.

Foille
Other information

Avoid contact with clothing

Foille may stain certain fabrics

Foille
Inactive ingredients

beeswax, benzyl alcohol, calcium disodium EDTA, calcium hydroxide, ceresin, eugenol, hydrogenated vegetable oil, maleic anhydride, mono- and di-glycerides, PEG-32, purified water, sodium borate, sodium lauryl sulfate, zea mays (corn) oil.

Burn Jel
Active ingredient

Lidocaine HCl 2.0 %v

Burn Jel
Purpose

External analgesic

Burn Jel
Uses

- temporarily relieves pain due to minor burns

Burn Jel
Warnings

For external use oonly

Do not use

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

When using this product

- avoid contact with eyes

Stop use and ask a doctor if

- the condition gets worse
- symptoms persist for more than 7 days
- condition clears up and recurs within a few days

Keep out of reach of children

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

Burn Jel
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
- you may report a serious reaction to this product to 800-430-5490

Burn Jel
Other information
- store at room temperature - do not use if opened or torn

Burn Jel
Inactive ingredients

carbopol 940, carbopol 1342, diazolidinyl urea, glycerin, melaleuca alternifolia (tea tree) leaf oil, methylparaben, octoxynol-9, propylene glycol, propylparaben, trolamine, water

Burn Jel
Questions

1-800-430-5490

Sting Relief
Active ingredients (in each wipe)

Ethyl alcohol 50.0%

Lidocaine HCl 2.0%

Sting Relief
Purpose

Antiseptic

Topical pain relief

Sting Relief
Uses
- prevent infection in minor scrapes, and temporary relief of itching of insect bites

Sting Relief
Warnings

For external use only

Flammable, keep away from open fire or flame

Do not use
- over large areas of the body
- in eyes

- over raw or blistered areas

Stop use and ask a doctor

if conditions worsen or persist for 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.

Sting Relief
Directions

- adults and children 2 years and older: Apply to cleaned affected area not more than 3 times daily.
- children under 2 years of age: consult a doctor.

Sting Relief
Inactive ingredients

benzalkonium chloride, menthol, and purified water

Sting Relief
Questions or Comments?

1-800-430-5490

PVP Wipe
Active ingredient

Povidone-iodine 10% (equivalent to 1% titratable iodine)

PVP
Purpose

First aid antiseptic

PVP
USes

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

PVP
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

- condition worsens or persists for more than 72 hours
- irritation and redness develops

Keep out of reach of children.

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

PVP
Directions

- clean the affected area
- apply1 to 3 times daily
- may be covered with a sterile bandage
- if bandaged, let dry first
- discard wipe after single use

PVP
Other information

- do not use on individuals who are allergic or sensitive to iodine
- store at controlled temperature 59-86ºF (15-30ºC)
- do not use if pouch is open or torn

PVP
Inactive ingredients

nonoxynol 9, water

PVP
Questions

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

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.

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

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

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 ingredients

water

BZK
Questions

1-800-430-5490

4334
Z019819 KIT CONTENTS

1 TRIPLE ANTIBIOTIC 10 PER

1 INSTANT COLD PACK 4" X 6"

2 ADHESIVE BDG,PLSTIC,1"X3"16PER

1 BURN JEL 1/8 OZ, 6 PER

1 ALCOHOL PREP PADS 10P

1 PVP IODINE WIPES 10 PER

1 NITRILE GLOVES 2PR BBP

1 ANTIMCRBL ANTSPTC TWLETTS

1 ADHESIVE TAPE W/P 1/2"X 5 YD

1 TWEEZER PLASTICS 4"

1 FLEXICON 2"X 4.1 YD

1 FIRST AID GUIDE ASHI

1 ABD COMBINE PAD 5" X 9"

1 SCISSOR BDGE 4" RED PLS HDL

LBL STOCK 6-3/8"X4"

LBL STOCK 4"X2-7/8"

1 LBL STOCK 3"x1-7/8"

1 LBL CONTS 6 3/4"X3 1/2" ID B

1 LABEL COVER, GRAINGER Z019819

1 KIT PP 24 UNIT FA

3 SAFETEC STING RELIEF WIPES BULK

1 FOILLE BURN/F A OINT 1/2 OZ

4 GAUZE PADS 2"X2" 12PLY

1 GAUZE PADS 4"X4" 12PLY

4 WOVEN FINGERTIP BANDAGE 2"

4 WOVEN KNUCKLE BANDAGE

4 HEAVY FLEX LARGE PATCH 2" X 3"

1 GAUZE PADS 3"X3" 4/BX

1 TRIANG 37X37X52 UNIT

8 AYPANAL EXTRA BULK 2/PK

4379
Z63158002 Kit Contents

1 TRIPLE ANTIBIOTIC 10 PER

1 INSTANT COLD PACK 4" X 6"

2 ADHESIVE BDG,PLSTIC,1"X3"16PER

1 BURN JEL 1/8 OZ, 6 PER

1 ALCOHOL PREP PADS 10P

1 PVP IODINE WIPES 10 PER

1 NITRILE GLOVES 2PR BBP

1 ANTIMCRBL ANTSPTC TWLETTS

1 ADHESIVE TAPE W/P 1/2"X 5 YD

1 TWEEZER PLASTICS 4"

1 FLEXICON 2"X 4.1 YD

1 FIRST AID GUIDE ASHI

1 ABD COMBINE PAD 5" X 9"

1 SCISSOR BDGE 4" RED PLS HDL

LBL STOCK 6-3/8"X4"

LBL STOCK 4"X2-7/8"

1 LBL STOCK 3"x1-7/8"

1 LBL CONTS 6 3/4"X3 1/2" ID B

1 LABEL COVER, GRAINGER Z019819

1 KIT PP 24 UNIT FA

3 SAFETEC STING RELIEF WIPES BULK

1 FOILLE BURN/F A OINT 1/2 OZ

4 GAUZE PADS 2"X2" 12PLY

1 GAUZE PADS 4"X4" 12PLY

4 WOVEN FINGERTIP BANDAGE 2"

4 WOVEN KNUCKLE BANDAGE

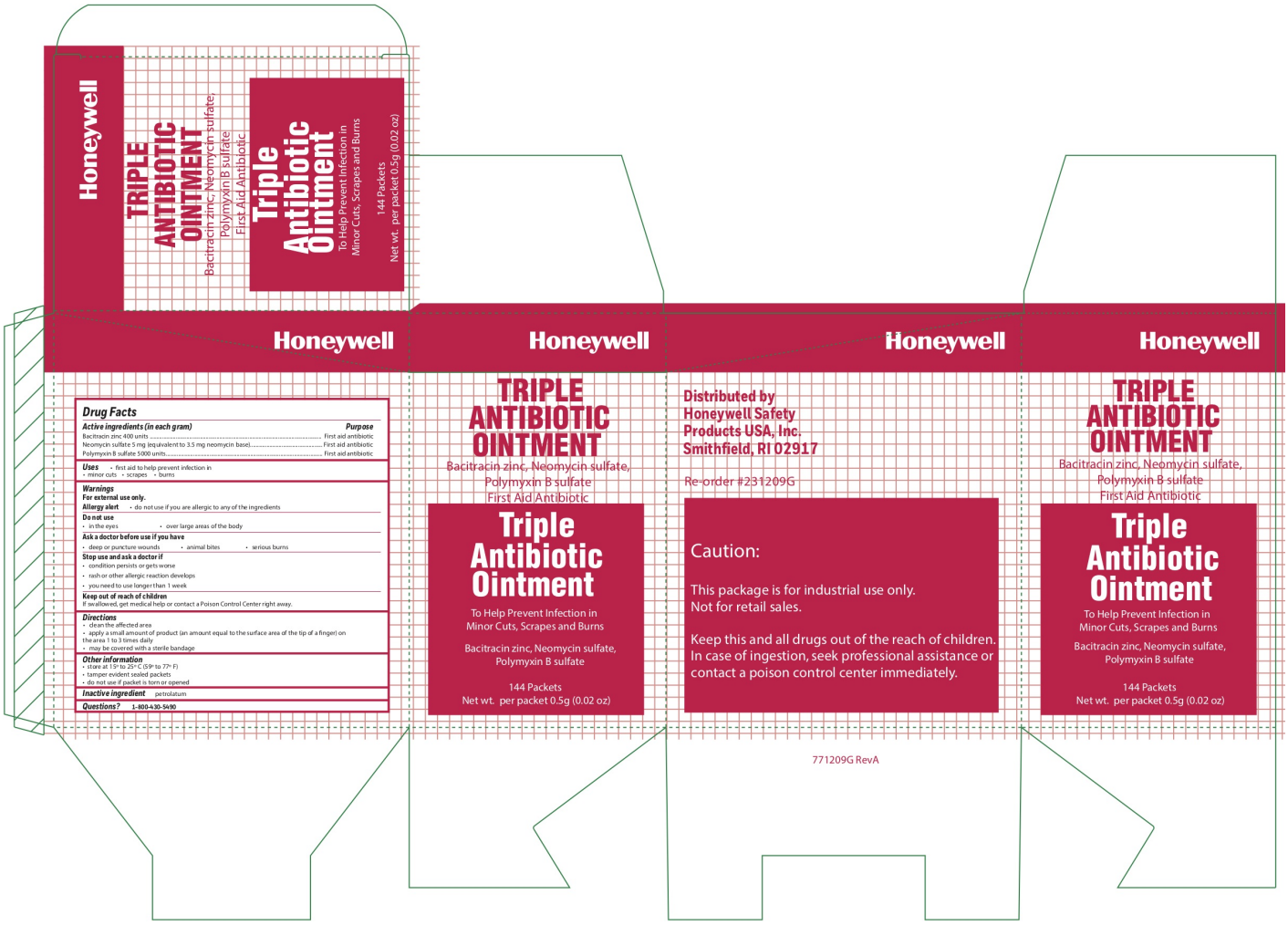
4 HEAVY FLEX LARGE PATCH 2" X 3"

1 GAUZE PADS 3"X3" 4/BX

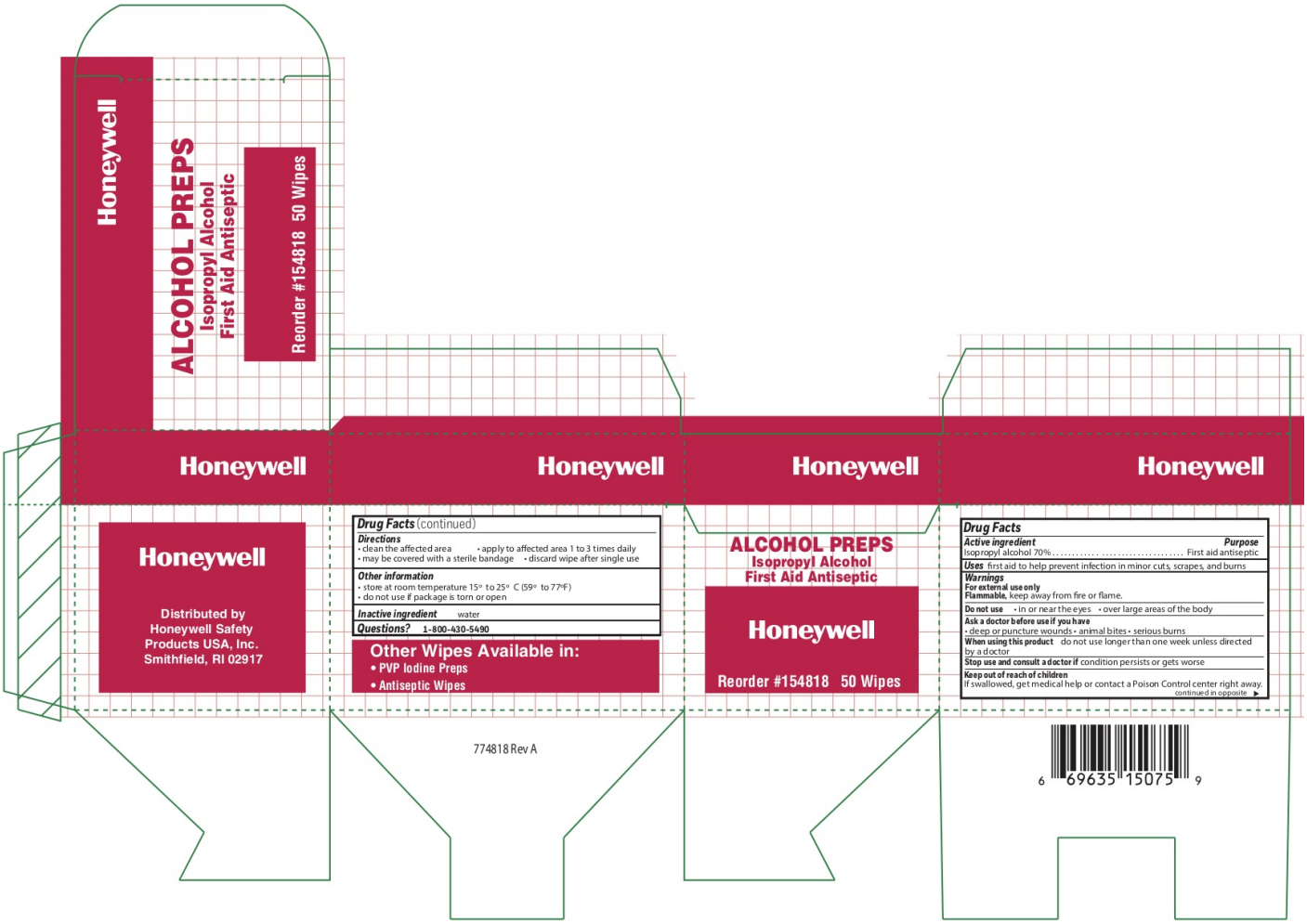
1 TRIANG 37X37X52 UNIT

8 AYPANAL EXTRA BULK 2/PK

Triple
Principal Display Panel



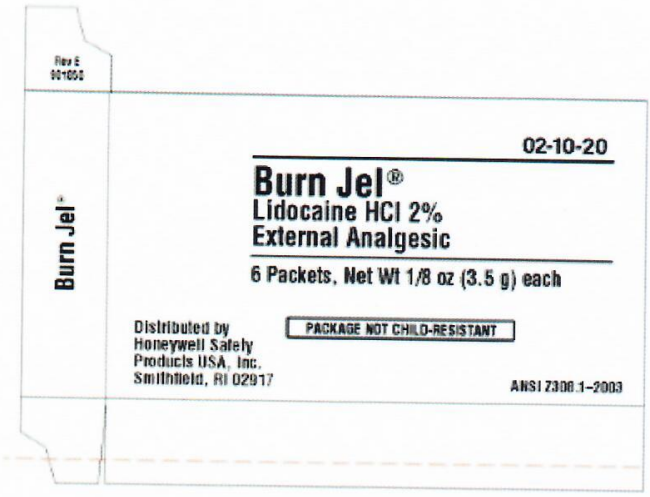
Alcohol
Principal Display Panel

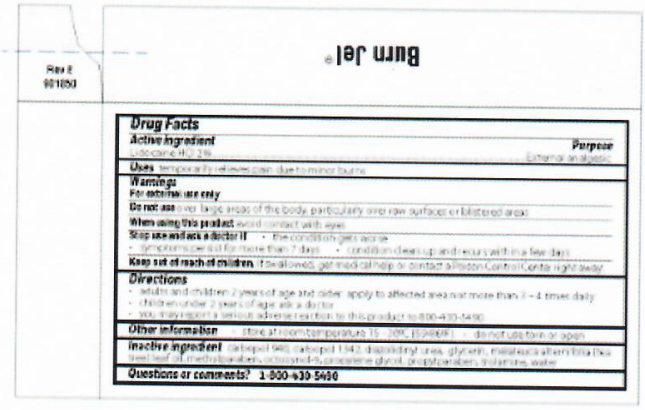


Foille

Principal Display Panel

Burn Jel
Principal Display Panel



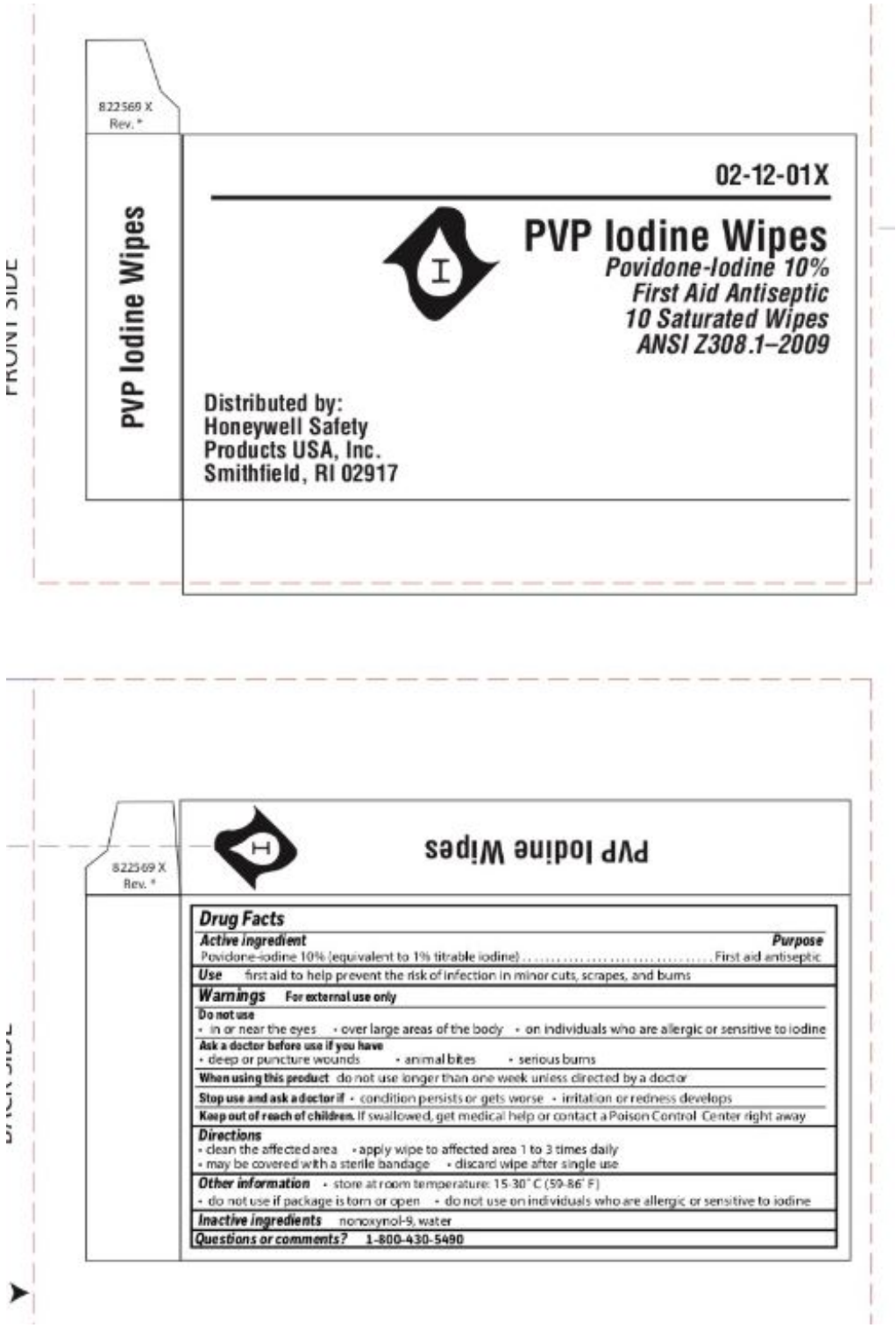


Sting Relief

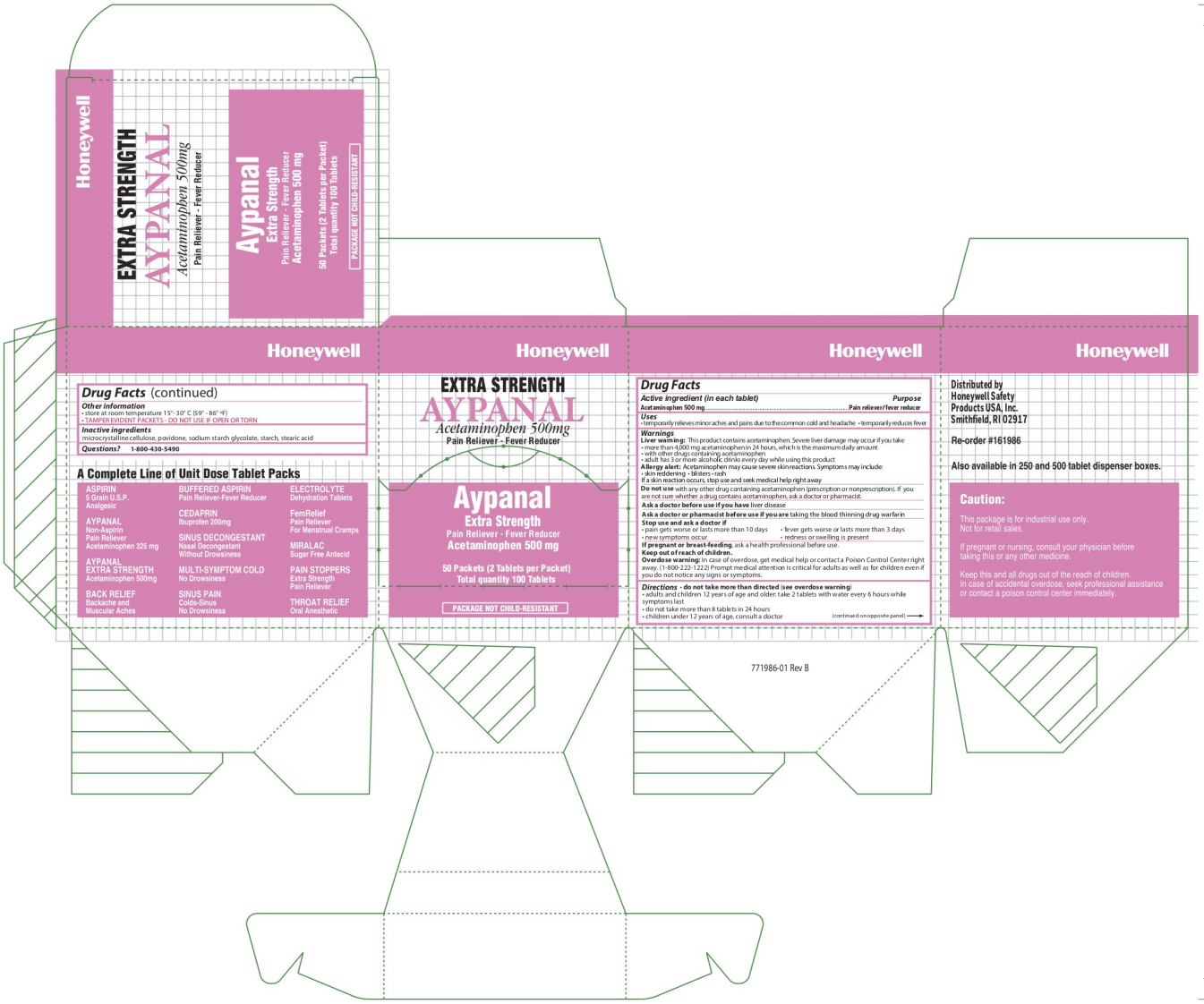
Principal Display Panel

PVP

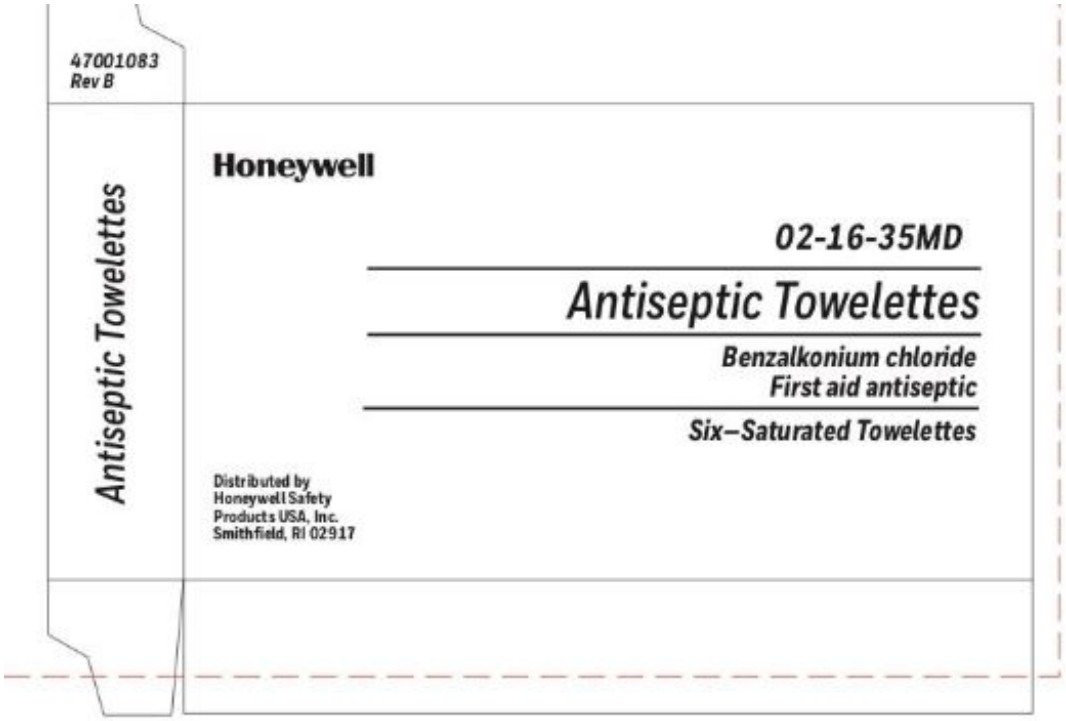
Principal Display Panel

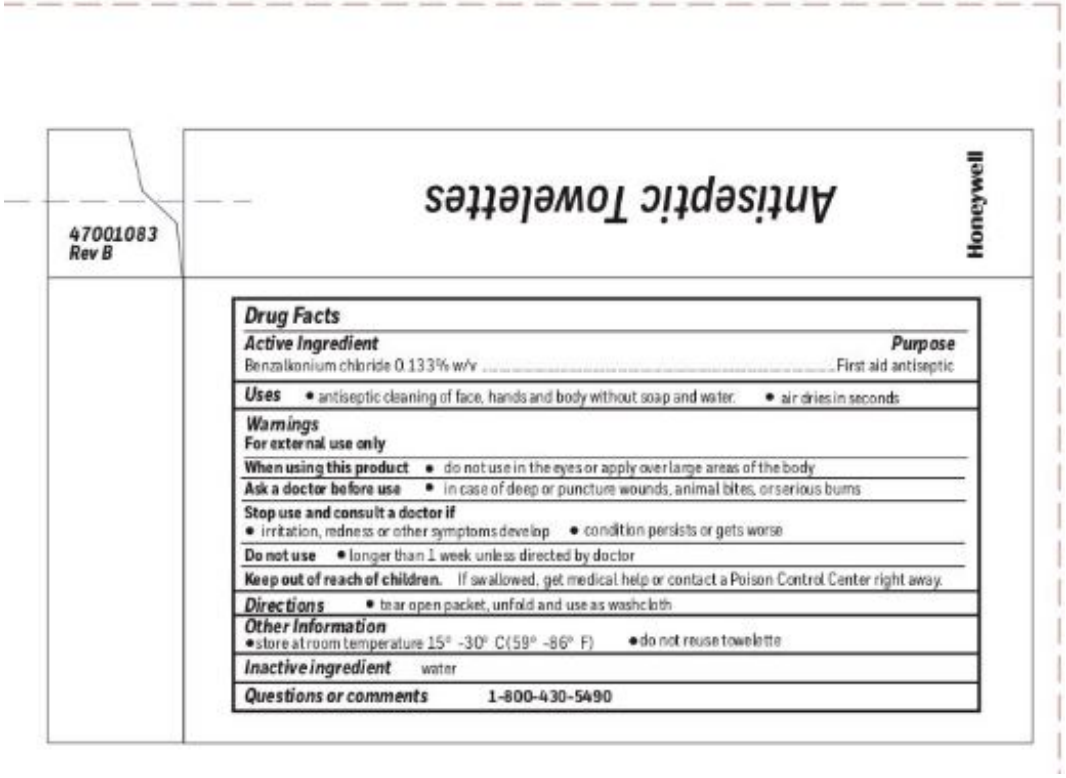


Aypanal EX
Principal Display Panel



BZK
Principal Display Panel





4334 Kit Label
Z019819

4373 Kit Label
Z63158002

46001363 Rev.C
Prints 3 colors
Black, Red (PMS 186) and Blue (PMS 072)

4379 FIRST AID KIT

4379 first aid kit kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0498-4379

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0498-4379-01	1 in 1 KIT; Type 0: Not a Combination Product	10/18/2018	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	10 POUCH	4 mL
Part 2	1 TUBE	14 g
Part 3	6 PACKET	21 g
Part 4	1 PACKET	1.4 mL
Part 5	3 POUCH	1.2 mL
Part 6	10 POUCH	3 mL
Part 7	8 PACKET	16
Part 8	10 PACKET	9 g

Part 1 of 8

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 8

BLISTEX FOILLE MEDICATED FIRST AID

benzocaine and chloroxylenol ointment

Product Information

Item Code (Source)	NDC:10157-9302
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	0.1 g in 100 g
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CERESIN (UNII: Q1LS2UJO3A)	
EUGENOL (UNII: 3T8H1794QW)	
MALEIC ANHYDRIDE (UNII: V5877ZJZ25)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
CORN OIL (UNII: 8470G57WFM)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CALCIUM HYDROXIDE (UNII: PF5DZW74VN)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		14 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/05/2013	

Part 3 of 8

BURN JEL

gel for burns gel

Product Information	
Item Code (Source)	NDC:0498-0203
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	2 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
TEA TREE OIL (UNII: VIF565UC2G)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0203-00	3.5 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
unapproved drug other		09/19/2018	

Part 4 of 8

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		12/21/2017	

Part 5 of 8

STING RELIEF PAD

ethyl alcohol, lidocaine swab

Product Information	
Item Code (Source)	NDC:0498-0733
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	20 mg in 1 mL
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.5 mL in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
MENTHOL (UNII: L7T10EIP3A)	
WATER (UNII: 059QF0KO0R)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		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		12/23/2017	

Part 6 of 8

PVP IODINE WIPE

povidone-iodine 10% swab

Product Information	
Item Code (Source)	NDC:0498-0121
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
NONOXYNOL-9 (UNII: 48Q180SH9T)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0498-0121-00	0.3 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

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

Part 7 of 8

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

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 8 of 8

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	

Marketing Information

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

4334 FIRST AID KIT

4334 first aid kit kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0498-4334

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4334-01	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 PACKET	1.4 mL
Part 2	3 POUCH	1.2 mL
Part 3	10 POUCH	3 mL
Part 4	8 PACKET	16
Part 5	10 PACKET	9 g
Part 6	10 POUCH	4 mL
Part 7	1 TUBE	14 g
Part 8	6 PACKET	21 g

Part 1 of 8

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		12/21/2017	

Part 2 of 8

STING RELIEF PAD

ethyl alcohol, lidocaine swab

Product Information	
Item Code (Source)	NDC:0498-0733
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	20 mg in 1 mL
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.5 mL in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
MENTHOL (UNII: L7T10EIP3A)	
WATER (UNII: 059QF0KO0R)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		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		12/23/2017	

Part 3 of 8

PVP IODINE WIPE

povidone-iodine 10% swab

Product Information	
Item Code (Source)	NDC:0498-0121
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
NONOXYNOL-9 (UNII: 48Q180SH9T)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0498-0121-00	0.3 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

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

Part 4 of 8

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

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 5 of 8

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 6 of 8

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 7 of 8

BLISTEX FOILLE MEDICATED FIRST AID

benzocaine and chloroxylenol ointment

Product Information

Item Code (Source)	NDC:10157-9302
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	0.1 g in 100 g
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955)	
CERESIN (UNII: Q1LS2UJO3A)	
EUGENOL (UNII: 3T8H1794QW)	
MALEIC ANHYDRIDE (UNII: V5877ZJZ25)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
CORN OIL (UNII: 8470G57WFM)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CALCIUM HYDROXIDE (UNII: PF5DZW74VN)	

WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		14 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/05/2013	

Part 8 of 8

BURN JEL

gel for burns gel

Product Information

Item Code (Source)	NDC:0498-0203
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
TEA TREE OIL (UNII: VIF565UC2G)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
GLYCERIN (UNII: PDC6A3C0OX)	

METHYLPARABEN (UNII: A2I8C7HI9T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0203-00	3.5 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
unapproved drug other		09/19/2018	

Marketing Information

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

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