### 4280 FIRST AID KIT- 4280 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.

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4280 First Aid Kit (BZK wipes, FABC, triple, PVP wipe- SF00002263)

# First Aid Burn Cream *Active ingredient*

Benzalkonium chloride o.13%

Lidocaine HCl 0.5%

## First Aid Burn Cream *Purpose*

First aid antiseptic

External analgesic

#### First Aid Burn Cream

#### Uses

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

## First Aid Burn Cream 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

#### First Aid Burn Cream

#### 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

#### First Aid Burn Cream

#### Other information

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

#### First Aid Burn Cream

#### **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

## First Aid Burn Cream Questions

1-800-430-5490

### Triple

#### Active ingredient (each gram contains)

Bacitracin zinc 400 units - Neomycin sulfate (5 mg equivalent to 3.5 mg Neomycin base) Polymyxin B sulfate 5000 units

## Triple *Purpose*

First aid antibiotic First aid antibiotic First aid antibiotic

## Triple

Uses

first aid to help prevent infection in

- minor cuts
- scrapes
- burns

#### **Triple**

**Warnings** 

#### For external use only

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

Do not use

- in the eyes
- over large areas of the body

### Ask a doctor before use if you have

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

#### Stop use and ask a doctor if

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

### Keep out of the reach of children

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

#### **Triple**

#### Directions

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

### **Triple**

#### Other information

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

## Triple

## **Inactive ingredient**

petrolatum

## Triple *Questions*

1-800-430-5490

#### **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

#### Keep out of reach of children

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

#### Stop use and ask a doctor if

- irritation, redness or other symptoms develop
- the condition persists or gets worse

#### **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

#### **PVP**

#### 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 59-86°F (15-30°C)
- do not use if pouch is open or torn

#### **PVP**

### **Inactive ingredients**

nonoxynol 9, water

#### **PVP**

#### **Questions**

1-800-430-5490

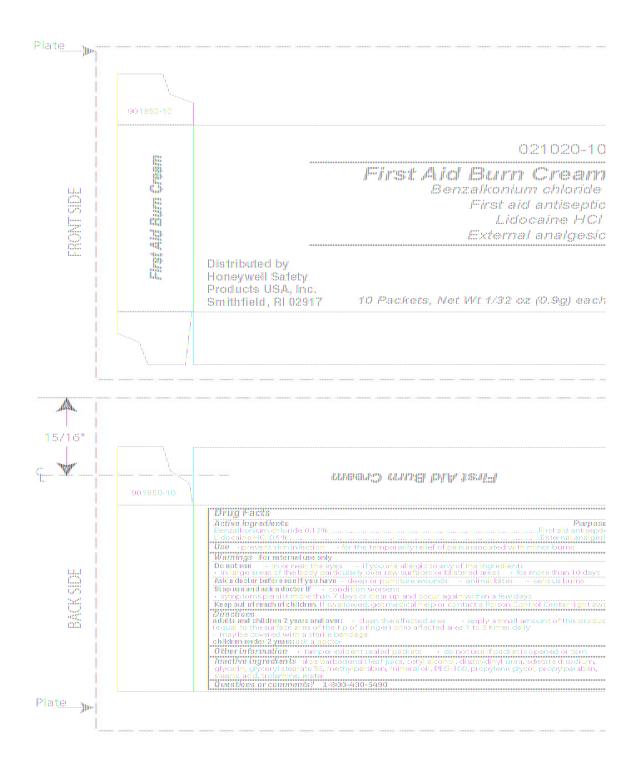
#### 4280

#### SF00002263 Kit Contents

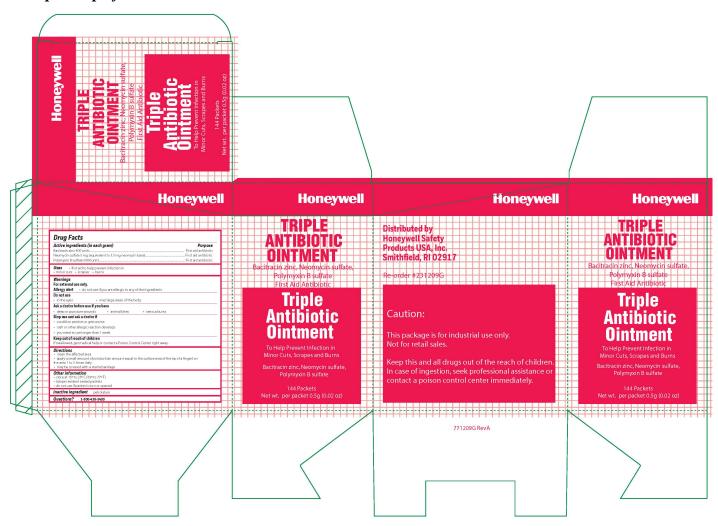
1 TRIPLE ANTIBIOTIC 10 PER

- 1 ADHESIVE TPE 1"X2-1/2 YD 2 PER
- 1 GAUZE BANDAGE, 2" X 6 YD,2 PER
- 2 EYEWASH BOTTLES 1 OZ, UNITIZED 2/BX
- 1 BANDAGE COMP, 4" OFFSET, 1 PER
- 1 PVP IODINE WIPES 10 PER
- 1 ADH BDG, CLOTH, 1"X3", 16 PER
- 1 FIRST AID GUIDE ASHI
- 1 RESPONSE KIT BLOODBORNE PATHOG
- 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"
- 2 PR LRG NITRILE GLVES ZIP BAG
- 1 KIT, PP 16 UNIT FA
- 1 TRI BNDG NON WOVEN 40"X40"X56"
- 1 COLD PACK UNIT 4"X6" BULK
- 1 GZE PAD 3X3 10 2 UNIT
- 1 FIRST AID CREAM 10

First Aid Burn Cream Principal Display Panel



## **Principal Display Panel**



BZK Principal Display Panel

S	Honeywell	
ette		02-16-35MD
оме	=	Antiseptic Towelettes
Antiseptic Towelettes		Benzalkonium chloride First aid antiseptic
tise		Six-Saturated Towelettes
An	Distributed by Honeywell Safety Products USA, Inc. Smithfield, RI 02917	

7001083 Rev B	Antiseptic Towelettes	Homowood
	Drug Facts	
	Active Ingredient Pt Benzalkonium chloride 0.133% w/v First aid an	irpose tiseptic
	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 overlarge areas of the body	
	Ask a doctor before use  In case of deep or puncture wounds, animal bites, or serious burns  Stop use and consult a doctor if Irritation, redness or other symptoms develop  condition persists or gets worse	_
	Do not use ● longer than I week unless directed by doctor	18
	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right	away.
	Directions • to ar 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	

PVP Principal Display Panel



4280 Kit Label SF00002263





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

## **4280 FIRST AID KIT**

4280 first aid kit kit

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0498-4280

## **Packaging**

l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:0498-4280-01	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 PACKET	9 g
Part 2	1 PACKET	1.4 mL
Part 3	10 PACKET	9 g
Part 4	10 POUCH	3 mL

## Part 1 of 4

## 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
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g
LIDO CAINE HYDRO CHLO RIDE (UNII: V13007Z41A) (LIDO CAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE	0.5 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6 DC9 Q16 7 V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230 OU9 XXE4)	
PEG-100 STEARATE (UNII: YD0 1N1999R)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
TROLAMINE (UNII: 903K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	

l	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	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 monograph not final	part333A	12/20/2017	

## Part 2 of 4

#### ANTISEPTIC TOWELETTE

benzalkonium chloride liquid

#### **Product Information**

Item Code (Source) NDC:0498-0501

Route of Administration TOPICAL

### **Active Ingredient/Active Moiety**

reave ingredient reave wrotery		
Ingredient Name	Basis of Strength	Strength
<b>BENZALKONIUM CHLORIDE</b> (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	<b>Marketing Start Date</b>	Marketing End Date
ı	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	09/18/2018	

## Part 3 of 4

#### 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
BACITRACIN ZINC (UNII: 89 Y4M234ES) (BACITRACIN - UNII:58 H6 RWO 52I)	BACITRACIN	400 [iU] in 1 g
POLYMYXIN B SULFATE (LINII: 19371312D4) (POLYMYXIN B - LINII:12VZ07196K)	POLYMYXIN B	5000 [iII] in 1 g

## **Inactive Ingredients**

Ingredient Name	Strength
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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
ı	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
OTC monograph final	part333B	09/19/2018	

## Part 4 of 4

## **PVP IODINE WIPE**

povidone-iodine 10% swab

#### **Product Information**

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

## **Active Ingredient/Active Moiety**

ı	Ingredient Name	Basis of Strength	Strength
	PO VIDO NE-IO DINE (UNII: 85H0 HZU99 M) (IO DINE - UNII:9679 TC07X4)	IODINE	10 mg in 1 mL

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HIACHVE	Ingredients

inactive ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
NONOXYNOL-9 (UNII: 48Q180SH9T)	

Packaging				
# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
1 NDC:0498-0121-00	0.3 mL in 1 POUCH; Type 0: Not a Combination Product			
<b>Marketing Inf</b>	ormation			
Marketing Category	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		09/18/2018		
Marketing Information				
Marketing Category	y 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(0498-4280)	

Establishment			
Name	Address	ID/FEI	Business Operations
Water-Jel Technologies		155522589	manufacture(0498-0903, 0498-0750)

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

Establishment						
Name	Address	ID/FEI	Business Operations			
Sion Medical Biotext		532775194	manufacture (0498-0121)			

Revised: 9/2019 Honeywell Safety Products USA, INC