4378 FIRST AID KIT- 4378 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.

0498-4378: First Aid Kit (FABC, EW, aypanal EX, BZK wipes, Sting relief - Z63158000)

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 (5 0 86 0 F)
- do not reuse towelette

BZK

Inactiave ingredient

water

BzK

Questions

1-800-430-5490

Aypanal

Active ingredient (in each tablet)

Acetaminophen 500 mg

Aypanal Purpose

Pain reliever/fever reducer

Aypanal

Uses

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

Aypanal *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.

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 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

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 Inactive igredients

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

Aypanal **Questions or Comments**

1-800-430-5490

FABC Active ingredient

Benzalkonium chloride 0.13%

Lidocaine HCI 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

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

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

Sting Relief Active ingredient (in eachwipe)

Ethyl alcohol 50.0%

Lidocaine HCl 2.0%

Sting Relief **Purpose**

Antiseptic

Topical pain relief

Sting Rellief

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

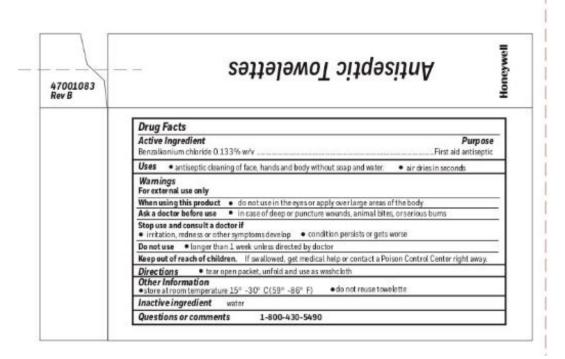
4378 **Z631580000 KIT CONTENTS**

- 1 INSTANT COLD PACK 4" X 6"
- 1 ADHESIVE TAPE W/P 1/2"X 5 YD
- 1 TWEEZER PLASTICS 4"
- 1 FIRST AID GUIDE ASHI
- 1 ABD COMBINE PAD 5" X 9"
- 1 CPR FILTERSHIELD 77-100
- 1 FIRST AID BURN CREAM 0.9 GRM PKT 20

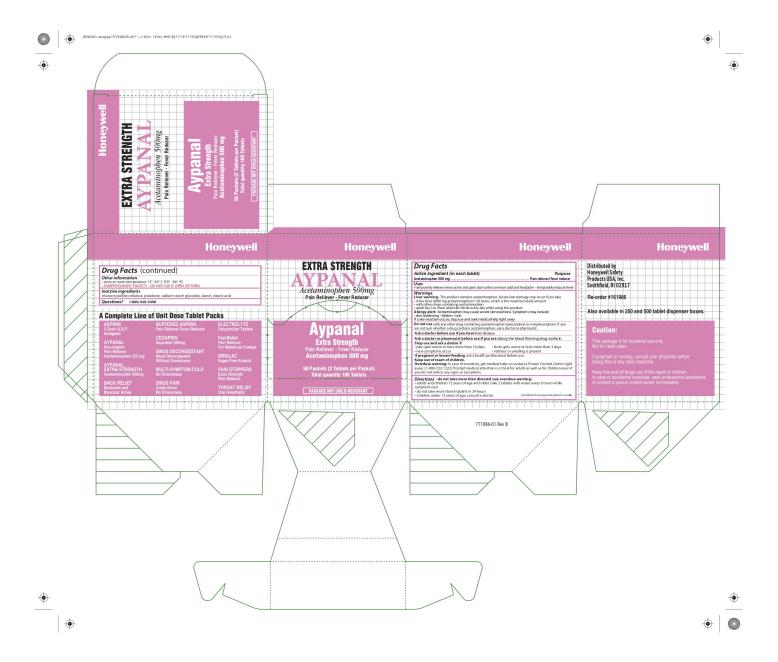
- 1 SCISSOR BDGE 4" RED PLS HDL
- 1 FANNY PACK RED FAK LOGO EMPTY
- 1 LBL STOCK 4"X2-7/8"
- 1 LBL STOCK 3"x1-7/8"
- 6 BZK ANTISEPTIC WIPE, BULK
- 1 1 PR LRG NITRILE GLVES ZIP BAG
- 1 1" X 3" PLASTIC BANDS 16/BAG
- 5 SAFETEC STING RELIEF WIPES BULK
- 1 TRI BNDG NON WOVEN 40"X40"X56"
- 3 GAUZE PADS 3"X3" 12PLY
- 2 HEAVY FLEX LARGE PATCH 2" X 3"
- 2 AYPANAL EXTRA BULK 2/PK

BZK Principal Display Panel

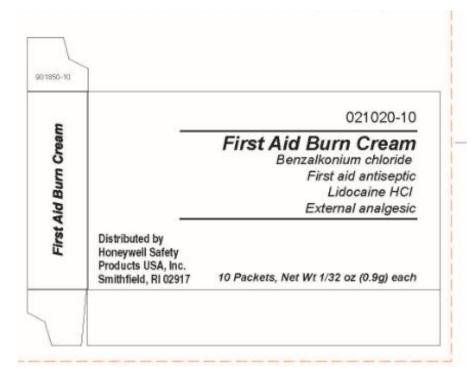
S	Honeywell	
lette		02-16-35MD
оме	=	Antiseptic Towelettes
Antiseptic Towelettes		Benzalkonium chloride First aid antiseptic
tise		Six-Saturated Towelettes
An	Distributed by Honeywell Safety Products USA, Inc. Smithfield, RI 02917	

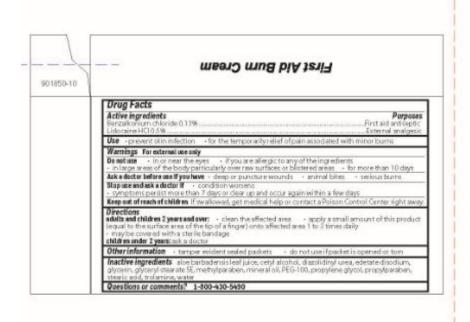


Aypanal *Principal Display Panel*

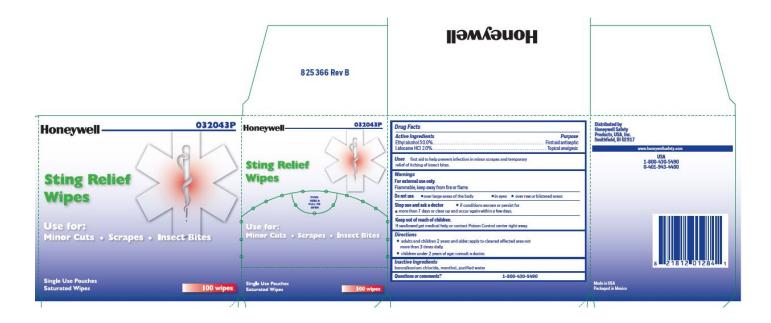


FABC Principal Display Panel





Sting Relief Principal Display Panel



4378 Kit Label Z631580000



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

APPROVED

4378 FIRST AID KIT

4378 first aid kit kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0498-4378

kaging

	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:0498-4378-01	1 in 1 KIT; Type 0: Not a Combination Product	10/18/2018	

Quantity of Parts

4	,		
Part #	Package Quantity	Total Product Quantity	
Part 1	5 POUCH	2 mL	
Part 2	6 PACKET	8.4 mL	
Part 3	2 PACKET	4	
Part 4	20 PACKET	18 g	

Part 1 of 4

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
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
MENTHOL (UNII: L7T10EIP3A)	
WATER (UNII: 0590F0KO0R)	

Packaging

#	rcem Code	Package Description	магкетіng этагт Date	магкетіng 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 2 of 4

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	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
	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 3 of 4

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: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) ACETAMINOPHEN 500 mg

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

Product Characterist	ics				
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 4 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			
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	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)		
PEG-100 STEARATE (UNII: YD01N1999R)		
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
WATER (UNII: 059QF0KO0R)		
LIGHT MINERAL OIL (UNII: N6K5787QVP)		
EDETATE DISODIUM (UNII: 7FLD91C86K)		
TROLAMINE (UNII: 903K93S3TK)		
GLYCERIN (UNII: PDC6A3C0OX)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)		

l	Pa	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 In	formation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/20/2017	

Marketing Ir	nformation		
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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