

4391 FIRST AID KIT- 4391 first aid
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.

0498-4391: First Aid Kit (alcohol wipes, HC cr, PVP wipes, sting relief-SF00003659/M)

Sting Relief
Active ingredient (in each wipe)

Ethyl alcohol 50.0%

Lidocaine HCl 2.0%

Sting Relief
Purposse

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

Hydrocortisone

Active ingredient (in each gram)

Hydrocortisone acetate (equivalent to Hydrocortisone 1%)

Hydrocortisone

Purpose

Anti-itch cream

Hydrocortisone

Uses

- for the temporary relief of itching associated with minor skin irritations and rashes

Hydrocortisone

Warnings

For external use only

Ask a doctor before use if

- you are using any other hydrocortisone product

When using the product

- avoid contact with eyes
- do not begin use of any other hydrocortisone product unless you have consulted a

doctor

- do not use for the treatment of diaper rash

Stop use and ask a doctor if

- condition worsens
- condition persists 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.

Hydrocortisone

Directions

- adults and children 2 years and older:
- clean the affected area
- apply to the area not more than 3 to 4 times daily
- children under 2 years of age: consult a doctor

Hydrocortisone

Other information

- store at room temperature (do not freeze)

Hydrocortisone

Inactive ingredients

cetyl alcohol, citric acid, diazolidinyl urea, edetate disodium, glycerin, glyceryl monostearate, methylparaben, mineral oil, polyethylene glycol, propylene glycol, propylparaben, purified water, stearic acid, trolamine

Hydrocortisone

Questions or Comments?

1-800-430-5490

Alcohol

Active ingredient

Isopropyl alcohol 70%

Alcohol

Purpose

First aid antiseptic

Alcohol

Uses

first aid to help prevent infection in

- minor cuts
- scrapes
- burns

Alcohol

Warnings

For external use only

Flammable, keep away from fire and flame

Do not use

- in or near 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 1 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
- may be covered with a sterile bandage
- apply wipe to affected area 1 to 3 times daily
- discard wipe after single use

Alcohol

Other information

- store at room temperature 15 ° to 25 ° C (59 ° to 77 ° F)
- do not use if packet is torn or opened

Alcohol

Inactive ingredient

water

Alcohol 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
- apply 1 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

4391

SF00003659/M Kit Contents

1 KNUCKLE BAND 8 PER
 2 TRIANGULAR BDG, NON-STERILE
 1 ADH TAPE, .5" X 2.5 YD, 2 PER
 1 FORCEPS & SCISSORS, 1 EA
 2 GAUZE BANDAGE, 2" X 6 YD, 2 PER
 1 GAUZE COMP, 1 SQ YARD, 1 PER
 1 INSTANT COLD PACK 4" X 6"
 1 BANDAGE COMP, 2" OFFSET, 4 PER
 1 BANDAGE COMP, 4" OFFSET, 1 PER
 1 FINGERTIP BANDAGE, 10 PER
 2 WATER JEL DRESSING, 2" X 2"
 2 WATER JEL DRESSING, 2" X 6"
 1 ALCOHOL PREP PADS 10P
 1 HYDROCORTISON, 1.0%, 1/32 OZ, 10P
 3 PVP IODINE WIPES 10 PER
 1 IVYX CLEANSER TOWEL 5 PER
 1 NITRILE GLOVES 2PR BBP
 2 ADH BDG, CLOTH, 1"X3", 16 PER
 1 CPR FILTERSHIELD 77-100
 LBL STOCK 6-3/8"X4"
 LBL STOCK 4"X2-7/8"

1 LBL STOCK 3"x1-7/8"

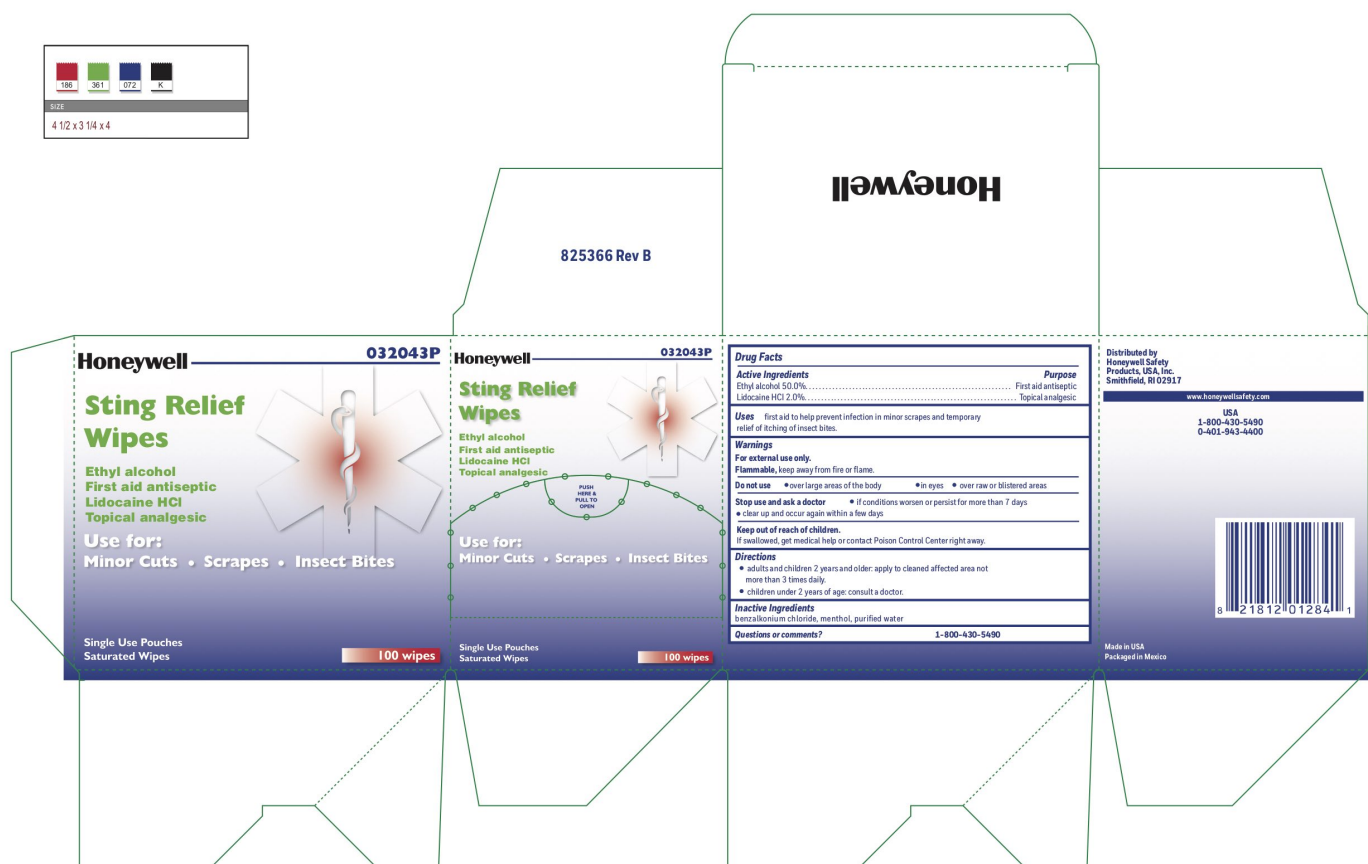
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1 KIT STL 36 UN WHT 01 HOR SHELF

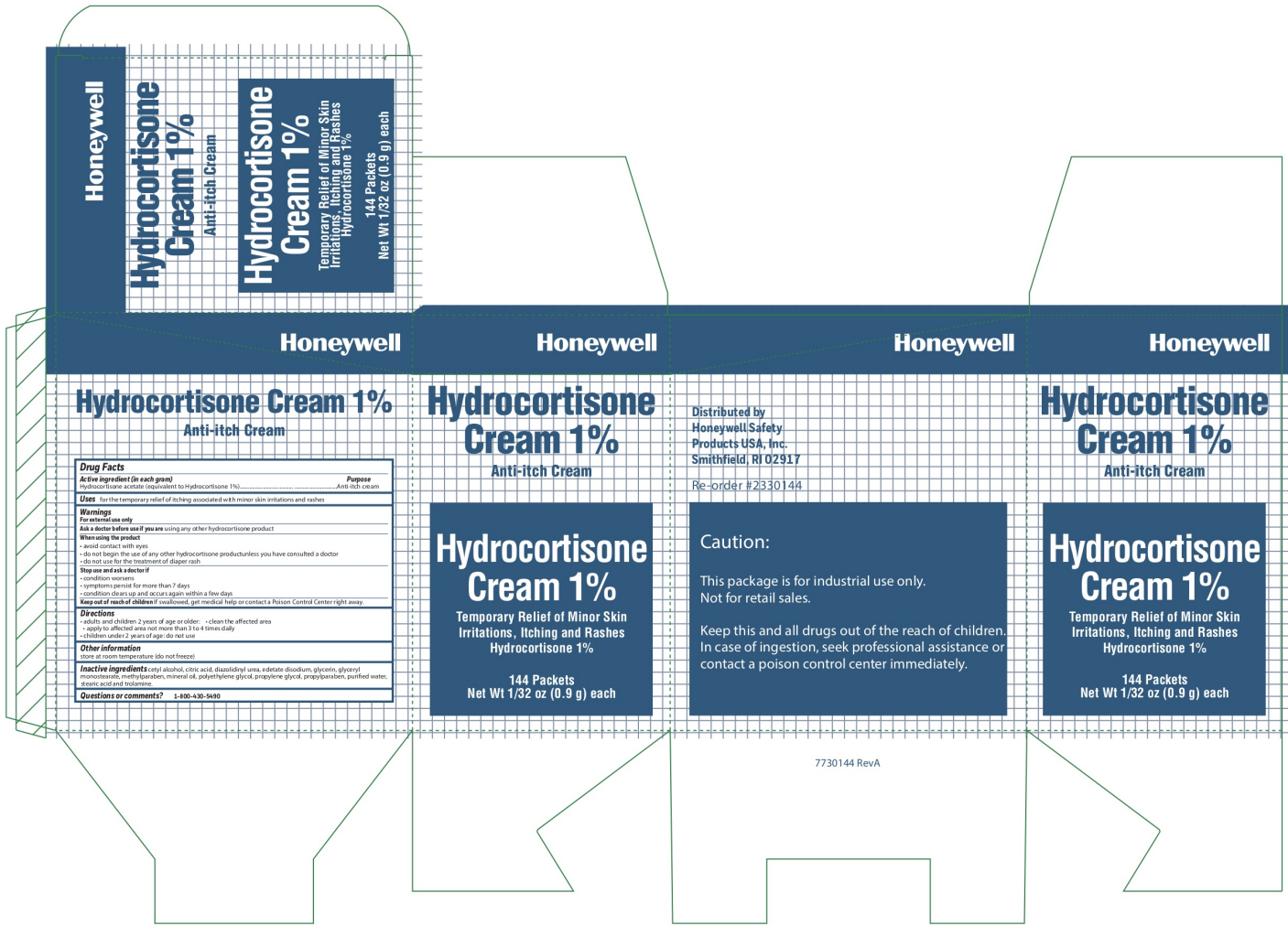
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1 STING Relief WIPES 10

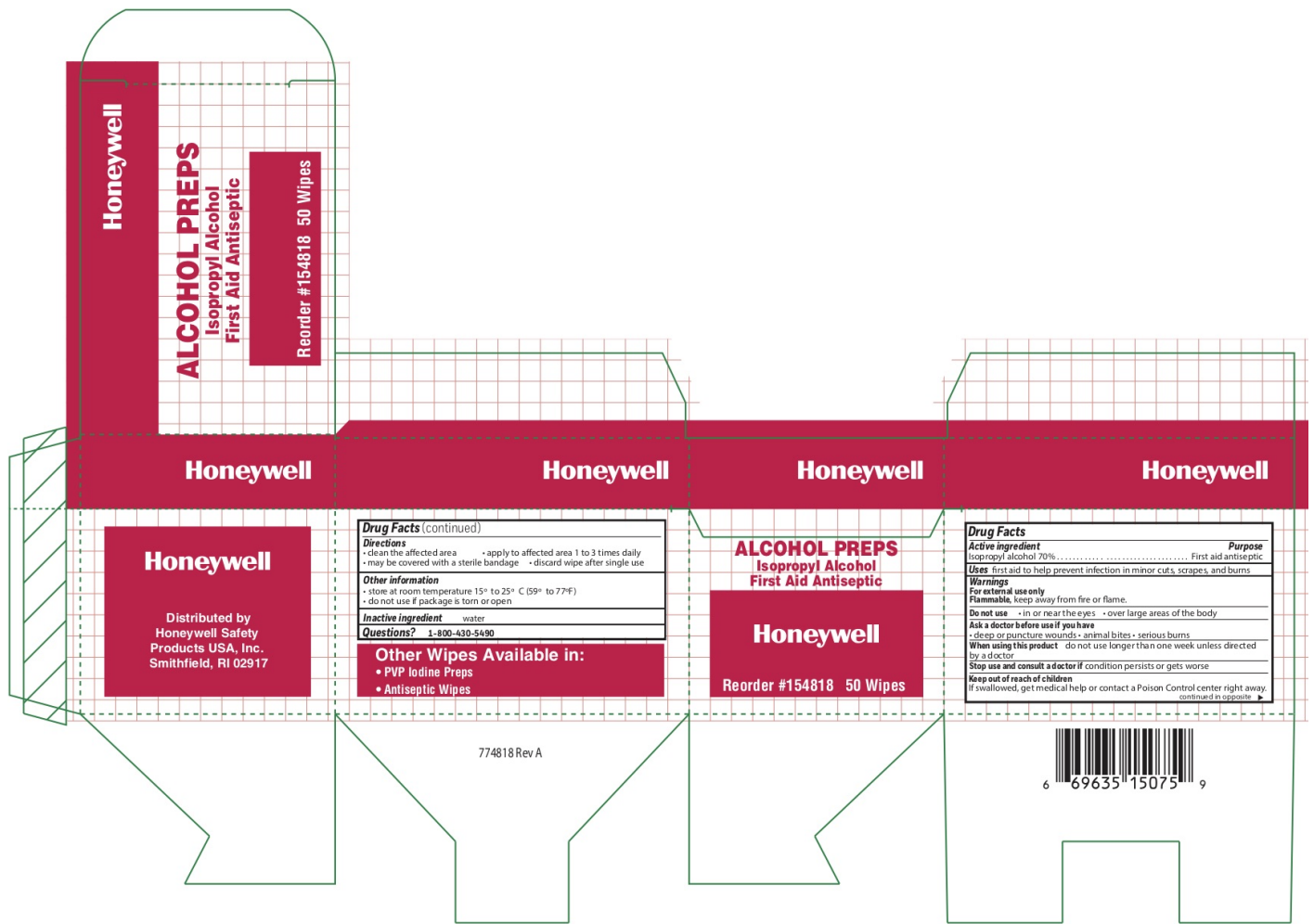
Sting Relief Principal Display Panel



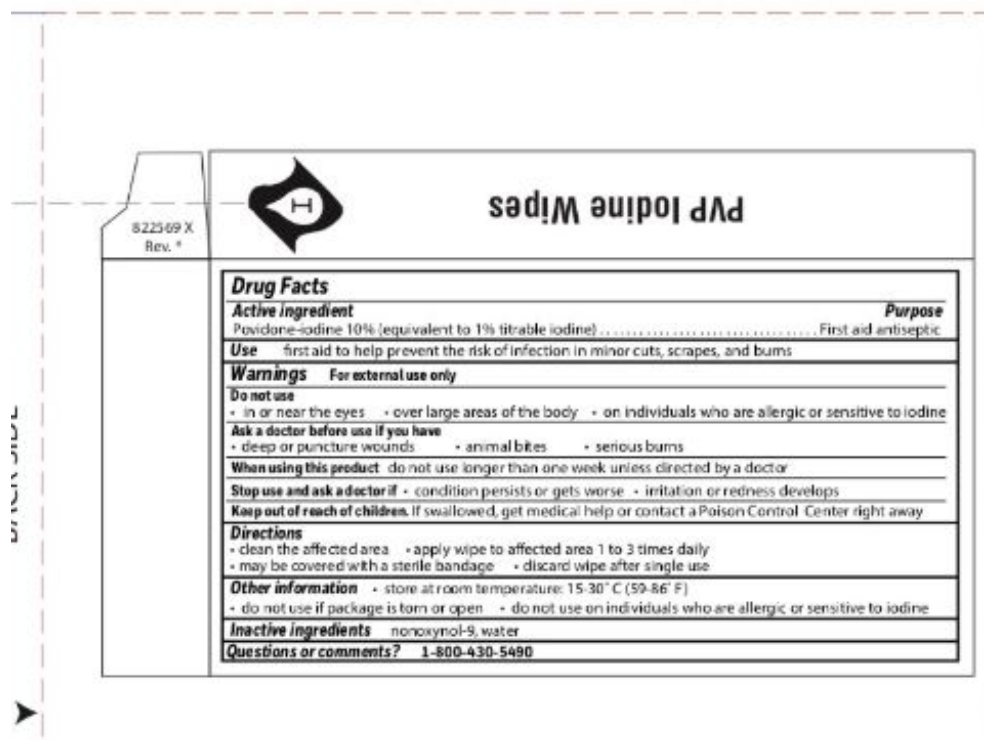
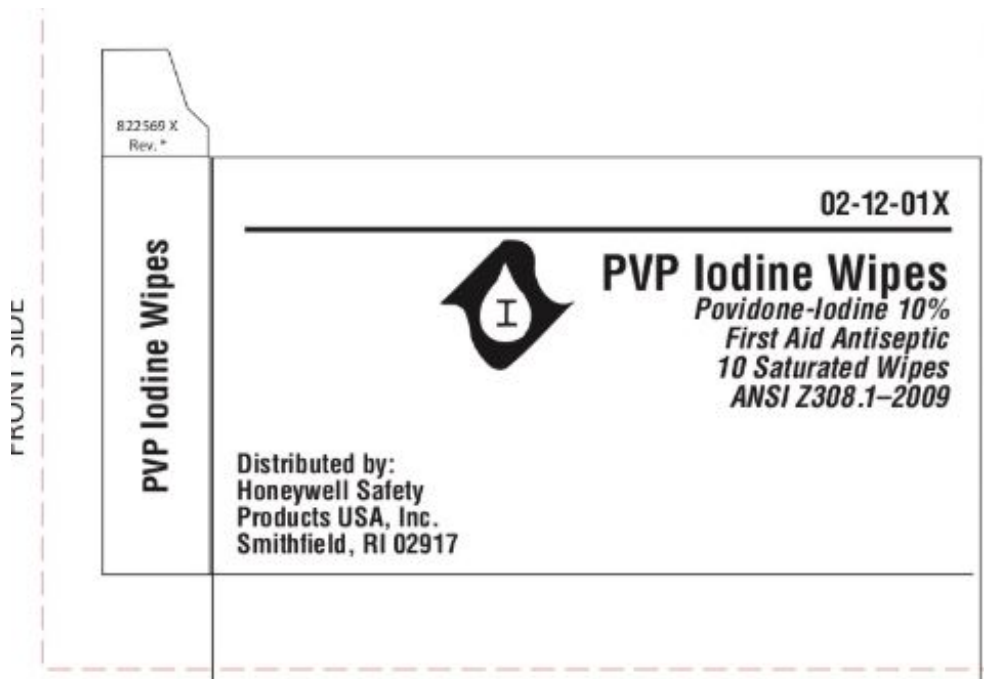
Hydrocortisone Principal Display Panel



Alcohol
Principal Display Panel



PVP
Principal Display Panel



4391 Kit Label
SF00003659/M

777027 Rev. D
4 color process, pms 072 blue, and pms 186 red



4391 FIRST AID KIT

4391 first aid kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0498-4391
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4391-01	1 in 1 KIT	09/13/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	10 POUCH	4 mL
Part 2	10 POUCH	4 mL
Part 3	10 PACKET	9 g
Part 4	30 POUCH	9 mL
Part 5	10 PACKET	9 g

Part 1 of 5

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 5

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: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0733-00	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 5
HYDROCORTISONE anti-itch cream ointment

Product Information	
Item Code (Source)	NDC:0498-0800
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength

LIGHT MINERAL OIL (UNII: N6K5787QVP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
TROLAMINE (UNII: 9O3K93S3TK)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

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		03/06/2013	10/15/2019

Part 4 of 5	
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	
WATER (UNII: 059QF0KO0R)				
NONOXYNOL-9 (UNII: 48Q180SH9T)				
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 5 of 5				
HYDROCORTISONE				
anti-itch cream				
Product Information				
Item Code (Source)		NDC:0498-0801		
Route of Administration		TOPICAL		
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:W4X0X7BPJ)			HYDROCORTISONE ACETATE	1 g in 100 g
Inactive Ingredients				
Ingredient Name				Strength
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)				
TROLAMINE (UNII: 9O3K93S3TK)				
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)				
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
LIGHT MINERAL OIL (UNII: N6K5787QVP)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
CETYL ALCOHOL (UNII: 936JST6JCN)				

METHYLPARABEN (UNII: A2I8C7HI9T)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
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			10/15/2019	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other			09/13/2018	

Labeler - Honeywell Safety Products USA, Inc. (118768815)