

**4163 FIRST AID KIT - 4163 first aid kit**  
**4350 FIRST AID KIT - 4350 first aid kit**  
**4375 FIRST AID KIT - 4375 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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**4163, 4350, 4375 First Aid Kit (FABC, PVP wipes - 013055-4444, 018502-4220, Z018502-4220)**

### **First Aid Burn Cream**

#### ***Active ingredient***

Benzalkonium chloride 0.13%

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

### **Povidone Iodine Swab**

#### ***Active ingredient***

Povidone-iodine solution USP, 10% (equivalent to 1% titratable iodine)

### **Povidone Iodine Swab**

#### ***Purpose***

First aid antiseptic

### **Povidone Iodine Swab**

#### ***Uses***

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

### **Povidone Iodine Swab**

#### ***Warnings***

#### **For external use only**

#### **Do not use**

- over large areas of the body
- on individuals who are allergic or sensitive to iodine

#### **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 ask a doctor if**

- conditions persist or get worse
- irritation and redness develops

**Keep out of reach of children**

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

**Povidone Iodine Swab*****Directions***

Reverse cardboard sleeve, then crush at dot between thumb and forefinger. Allow solution to saturate tip and apply solution to injury.

- clean affected area
- apply to affected area 1 to 3 times daily
- may be covered with a sterile bandage
- discard swab after single use

**Povidone Iodine Swab*****Other information***

- store at room temperature away from light
- keep from freezing or excessive heat
- do not use if package is torn or open

**Povidone Iodine Swab*****Inactive ingredients***

citric acid, disodium phosphate, nonoxynol-9, sodium hydroxide, water

**Povidone Iodine Swab*****Questions and comments***

1-800-430-5490

**4163**

**013055-4444 Kit Contents**

1 FIRST AID BURN CREAM 6 PER

1 TRIANGULAR BDG, NON-STERILE

1 GAUZE PADS, 3" X 3", 4 PER

1 ADH TAPE, .5" X 2.5 YD, 2 PER

1 GAUZE COMP, 1 SQ YARD, 1 PER

1 ADHESIVE BDG, PLSTIC, 1" X 3" 16 PER

1 PVP IODINE WIPES 10 PER  
1 NITRILE GLOVES 2PR BBP  
LBL STOCK 6-3/8"X4"  
1 LBL STOCK 3"x1-7/8"  
1 LBL CONTS 6 3/4"X3 1/2" ID B  
1 KIT STL 10 UN WHITE 01

**4350**

**018502-4220 kit contents**

1 TRIANGULAR BDG, NON-STERILE  
1 GAUZE PADS, 3" X 3", 4 PER  
1 GAUZE COMP, 18" X 36", 2 PER  
1 TWEEZER PLASTICS 4"  
4 O/H PAK,ADH BDG 2"X4", X-LG  
1 FIRST AID GUIDE ASHI  
10 PVP PREP PADS MEDIUM  
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 1" X 3" PLASTIC BANDS 16/BAG  
6 FIRST AID CREAM 1.0GR PKT EACH  
2 TAPE ADHESIVE 1/2 X 2.5 125133  
1 KIT BAG SOFT PACK SMALL  
1 LBL CONTENTS ANSI Z308.1-2009 REV B  
1 COLD PACK UNIT 4"X6" BULK  
4 WOVEN FINGERTIP BANDAGE 2"  
4 WOVEN KNUCKLE BANDAGE

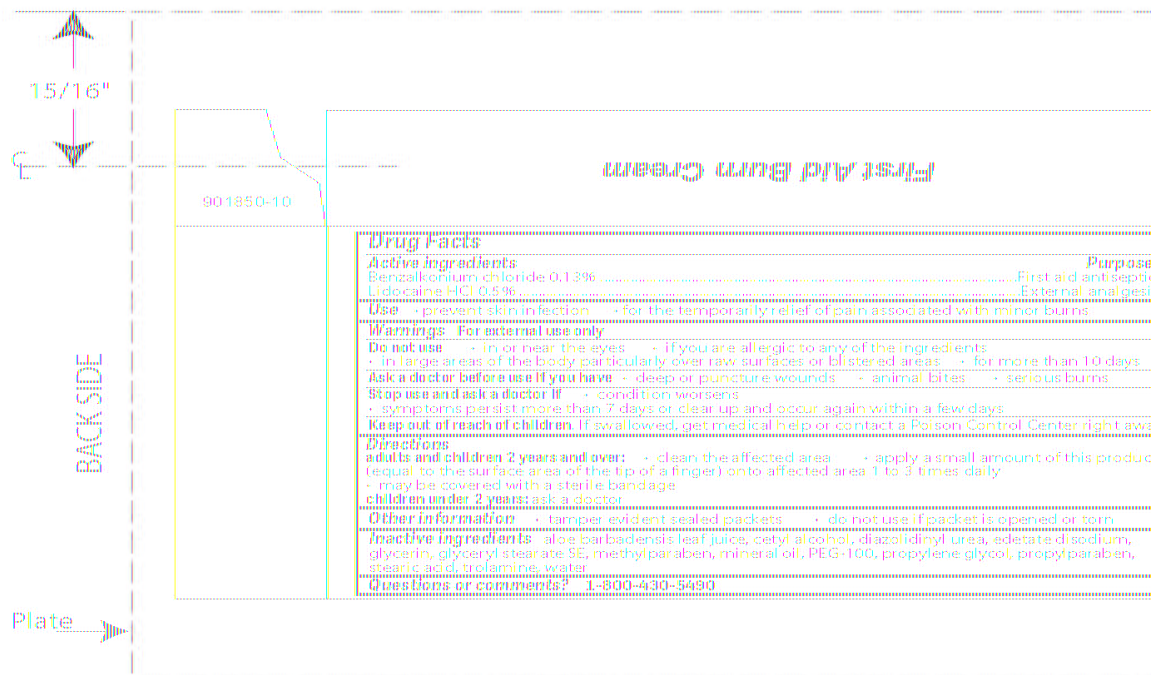
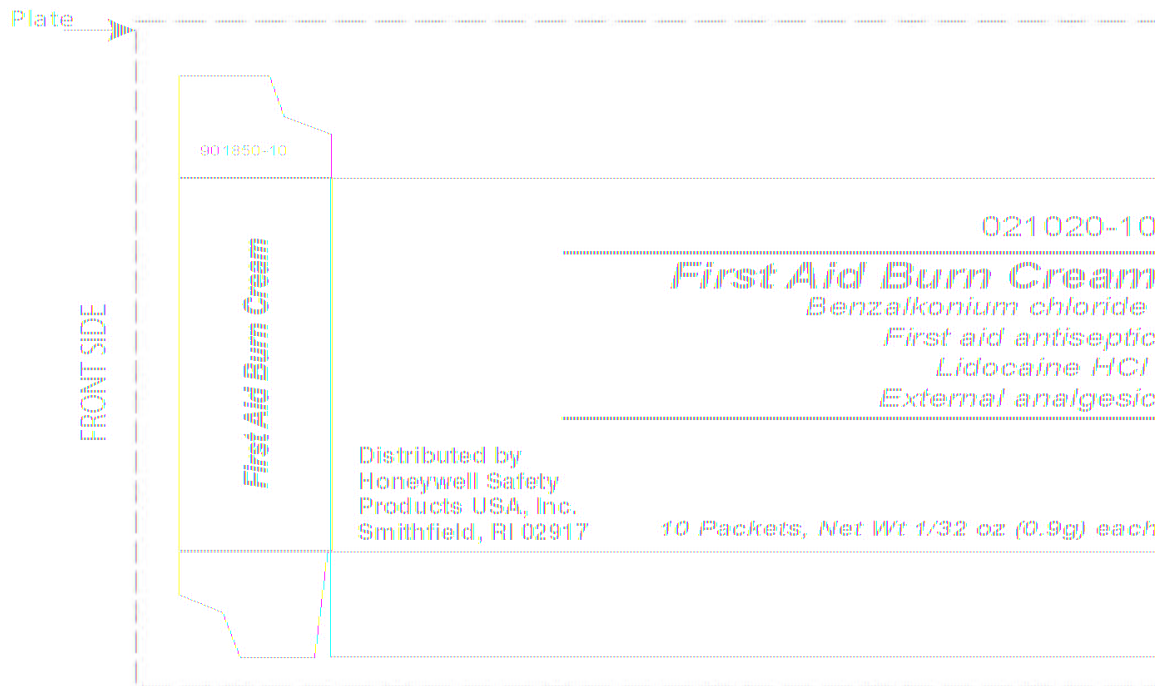
**4375**

**Z018502-4220**

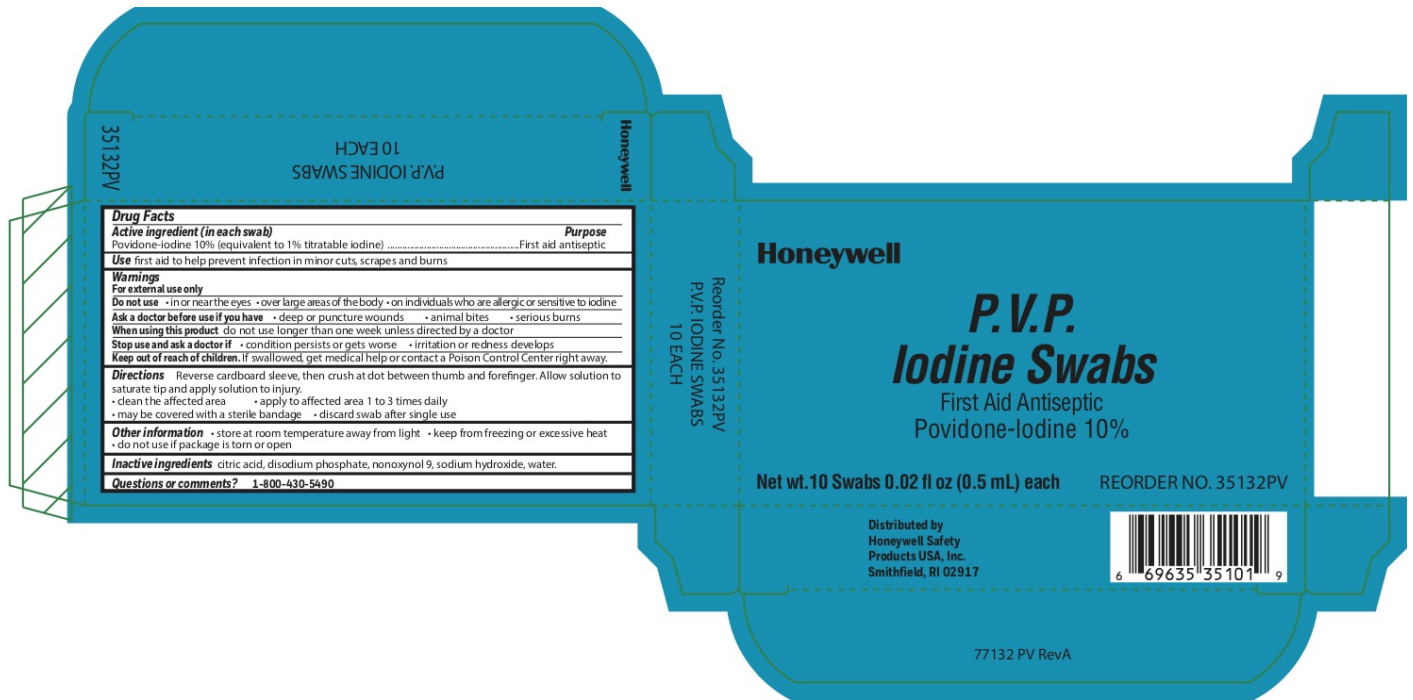
1 TRIANGULAR BDG, NON-STERILE  
1 GAUZE PADS, 3" X 3", 4 PER  
1 GAUZE COMP, 18" X 36", 2 PER  
1 TWEEZER PLASTICS 4"  
4 O/H PAK,ADH BDG 2"X4", X-LG  
1 FIRST AID GUIDE ASHI

10 PVP PREP PADS MEDIUM  
1 SCISSOR BDGE 4" RED PLS HDL  
LBL STOCK 6-3/8"X4"  
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1 KIT BAG SOFT PACK SMALL  
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1 COLD PACK UNIT 4"X6" BULK  
4 WOVEN FINGERTIP BANDAGE 2"  
4 WOVEN KNUCKLE BANDAGE

**First Aid Burn Cream**  
**Principal Display Panel**



# Principal Display Panel



4163 Kit Label  
013055-4444

46001403 Rev. C  
Prints 2 colors  
Black and Red (PMS 485)

## **Refill Information**

**US Poison Control 1-800-222-1222**

46001403 Rev. C

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



**Honeywell**

**First Aid Kit**

[www.honeywellsafety.com](http://www.honeywellsafety.com)

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

**4375 Kit Label**  
**Z018502-4220**

# **Honeywell**

## **First Aid Kit**

[www.honeywellsafety.com](http://www.honeywellsafety.com)

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

754002 Rev. D

# 4163 FIRST AID KIT

4163 first aid kit kit

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0498-4163
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4163-01	1 in 1 KIT; Type 0: Not a Combination Product	10/18/2018	

## Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	6 PACKET	5.4 g
Part 2	10 POUCH	3 mL

## Part 1 of 2

### FIRST AID BURN

benzalkonium chloride, lidocaine hydrochloride cream

## Product Information

Item Code (Source)	NDC:0498-0903
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Route of Administration	TOPICAL
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## 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)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0K00R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	

LIGHT MINERAL OIL (UNII: N6K5787QVP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	

### 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
OTC monograph not final	part333A	12/20/2017	

### Part 2 of 2

#### 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	

## Marketing Information

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

## 4350 FIRST AID KIT

4350 first aid kit kit

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0498-4350
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4350-01	1 in 1 KIT; Type 0: Not a Combination Product	10/18/2018	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	6 PACKET	5.4 g
Part 2	10 POUCH	3 mL

## Part 1 of 2

### 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)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	

## 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
OTC monograph not final	part333A	12/20/2017	

## Part 2 of 2

### 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
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NONOXYNOL-9 (UNII: 48Q180SH9T)

WATER (UNII: 059QF0K00R)

### 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	

### Marketing Information

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

## 4375 FIRST AID KIT

4375 first aid kit kit

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0498-4375
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4375-01	1 in 1 KIT; Type 0: Not a Combination Product	10/18/2018	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	6 PACKET	5.4 g
Part 2	10 POUCH	3 mL

## Part 1 of 2

### FIRST AID BURN

benzalkonium chloride, lidocaine hydrochloride cream

### Product Information

Item Code (Source)	NDC:0498-0903
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<b>Route of Administration</b>	TOPICAL
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### 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
<b>LIDOCAINE HYDROCHLORIDE</b> (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE	0.5 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>DIAZOLIDINYL UREA</b> (UNII: H5RIZ3MPW4)	

### 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
OTC monograph not final	part333A	12/20/2017	

### Part 2 of 2

**PVP IODINE WIPE**  
povidone-iodine 10% swab

### Product Information

<b>Item Code (Source)</b>	NDC:0498-0121
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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	

### 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 (079287321)

### Establishment

Name	Address	ID/FEI	Business Operations
Honeywell Safety Products USA, INC		079287321	pack(0498-4163, 0498-4350, 0498-4375)

### Establishment

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

### Establishment

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