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%)

Hydrcortisone *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 affeted are 1 to 3 times daily
- discard wipe after single use

Alcohol

Other information

- store at room temperature 15 0 to 25 0 C (59 0 to 77 0 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
- 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

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"

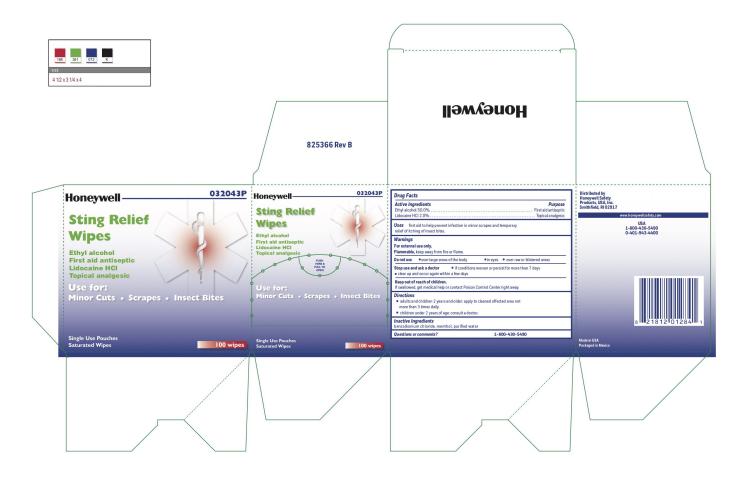
1 LBL STOCK 3"x1-7/8"

1 LABEL NORTH CONTENTS 8X8 ID B

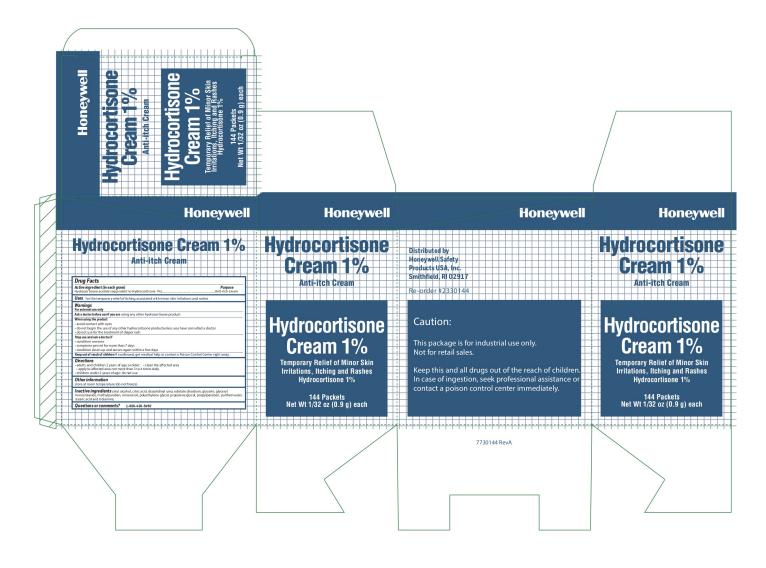
1 KIT STL 36 UN WHT 01 HOR SHELF

- 1 LBL 36U CVR NORTH ID C.
- 1 STING Relief WIPES 10

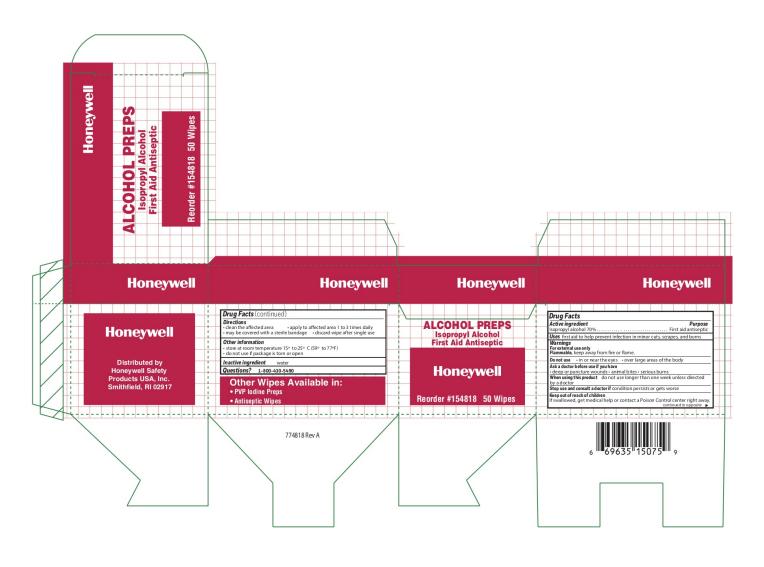
Sting Relief Principal Display Panel



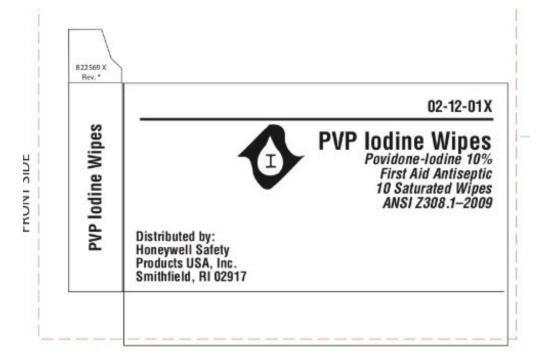
Hydrocortisone Principal Display Panel

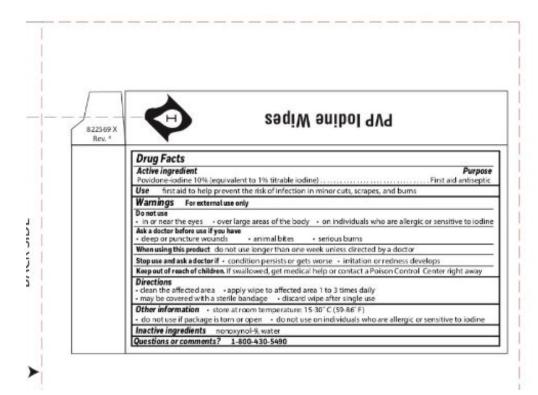


Alcohol Principal Display Panel



PVP Principal Display Panel





4391 Kit Label SF00003659/M



4391 FIRST AID KIT 4391 first aid kit **Product Information Product Type** HUMAN OTC DRUG Item Code (Source) NDC:0498-4391 Packaging **Package Description Marketing End Date** # Item Code **Marketing Start 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 Basis of Ingredient Name** Strength Strength ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL -ISOPROPYL 0.7 mL UNII:ND2M416302) ALCOHOL in 1 mL **Inactive Ingredients Ingredient Name** Strength WATER (UNII: 059QF0KO0R) Packaging Marketing Start **Marketing End** # Item Code **Package Description** Date Date **1** NDC:0498-0143-04 0.4 mL in 1 POUCH; Type 0: Not a Combination **Marketing Information Application Number or Monograph Marketing Start** Marketing End Marketing Citation Date Date Category unapproved drug 09/18/2018 other Part 2 of 5 STING RELIEF PAD ethyl alcohol, lidocaine swab **Product Information** Item Code (Source) NDC:0498-0733 **Route of Administration** TOPICAL

Active Ingredie	nt/Activo	Μοίοτν				
Active ingredie	Ingrediei		Ras	is of Streng	th	Strength
LIDOCAINE HYDRO(UNII:98PI200987)	-	NII: V13007Z41A) (LIDOCAINE -		HYDROCHLORI	DE 2	20 mg in 1 mL
ALCOHOL (UNII: 3K9	958V90M) (ALC	COHOL - UNII:3K9958V90M)	ALCOHOL).5 mL in 1 mL
Inactive Ingred	lients					
		Ingredient Name			Str	ength
BENZALKONIUM CH MENTHOL (UNII: L7T		: F5UM2KM3W7)				
WATER (UNII: 059QF	0KO0R)					
Packaging						
# Item Code	Pa	ckage Description		ing Start ate		ting End ate
).4 mL in 1 PO Product	UCH; Type 0: Not a Combination				
Marketing I	nformat	ion				
Marketing Category	Applicat	tion Number or Monograph Citation		eting Start Date		ting End ate
unapproved drug other			12/23/202	17		
Part 3 of 5						
HYDROCOR	TISONE					
anti-itch cream oi						
Product Inform	nation					
Item Code (Sourc	e)	NDC:0498-0800				
Route of Adminis	tration	TOPICAL				
Active Ingredie	ent/Active	Moiety				
	Ingre	edient Name		Basis of S	trength	Strengt
HYDROCORTISONE UNII:W4X0X7BPJ)	ACETATE (UN	III: 3X7931PO74) (HYDROCORTISOI		HYDROCORTIS ACETATE	ONE	1 g in 100 g
Inactive Ingred	lients					
		Ingredient Name			St	trength

		: N6K5787QVP)				
		, UNSPECIFIED (UNII: 3MQ0SDW1A)				
CETYL ALCO		· •				
		III: 6DC9Q167V3)				
STEARIC ACI		II: 7FLD91C86K)				
		ATE (UNII: 2300U9XXE4)				
TROLAMINE (
		I: H5RIZ 3MPW4)				
PROPYLPARA						
WATER (UNII:						
GLYCERIN (UI		RATE (UNII: 2968PHW8QP)				
D	_					
Packaging	J					
# Item Code		Package Description	Mark	ceting Start Date	Ма	rketing End Date
1	0.9 g in 1 l	PACKET; Type 0: Not a Combination				
	Product					
Marketi	ng Info	rmation				
Marketi Catego		Application Number or Monograph Citation	М	arketing Start Date	М	arketing End Date
unapproved dı other	rug		03/0	06/2013	10/1	5/2019
Part 4 o	f 5					
	INE WI	PE				
povidone-io						
Product I	nformativ	on				
Item Code (NDC:0498-0121				
Route of Ac						
Noute of At	ininisti a ti					
Active Ing	redient/A	Active Moiety				
		Ingredient Name		Basis of Stren	ngth	Strength
POVIDONE-IC		85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE		10 mg in 1 mL

WATER (UNII: 059Q		ngredient Name			Streng	gtn
NONOXYNOL-9 (UI	NII: 48Q1805H9	Τ)				
Packaging						
# Item Code	Pa	ckage Description		ting Start Date		ting End ate
1 NDC:0498-0121-	0.3 mL in 1 PC Product	UCH; Type 0: Not a Combination				
Marketing	Informat	ion				
-						tion of French
Marketing Category	Applica	tion Number or Monograph Citation	Mark	eting Start Date		ting End ate
unapproved drug other			09/18/20)18		
Part 5 of 5						
HYDROCOR	TISONE					
anti-itch cream						
Product Infor	mation					
Product Infor Item Code (Sour		NDC:0498-0801				
	rce)	NDC:0498-0801 TOPICAL				
ltem Code (Sou	rce)					
Item Code (Sour Route of Admini	rce) istration	TOPICAL				
ltem Code (Sou	rce) istration ient/Active	TOPICAL Moiety		Basis of S	itrength	Strengt
Item Code (Sour Route of Admini Active Ingredi	rce) istration ient/Active Ingra	TOPICAL Moiety edient Name	IE -	Basis of S	-	-
Item Code (Sour Route of Admini Active Ingredi HYDROCORTISON	rce) istration ient/Active Ingra	TOPICAL Moiety	ΙΕ -		-	Strengtl 1 g in 100 g
Item Code (Sour Route of Admini Active Ingredi HYDROCORTISON	rce) istration ient/Active Ingra	TOPICAL Moiety edient Name	IE -	HYDROCORTIS	-	1 g
Item Code (Sour Route of Admini Active Ingredi HYDROCORTISON UNII: W4X0X7BPJ)	rce) istration ient/Active ingra E ACETATE (U	TOPICAL Moiety edient Name	IE -	HYDROCORTIS	-	1 g
Item Code (Sour Route of Admini Active Ingredi	rce) istration ient/Active ingra E ACETATE (U	TOPICAL Moiety edient Name	IE -	HYDROCORTIS	ONE	1 g
Item Code (Sour Route of Admini Active Ingredi HYDROCORTISON UNII: W4X0X7BPJ)	rce) istration ient/Active ingra E ACETATE (UI	TOPICAL Moiety edient Name NII: 3X7931PO74) (HYDROCORTISON	IE -	HYDROCORTIS	ONE	1 g in 100 g
Item Code (Sour Route of Admini Active Ingredi HYDROCORTISON UNII: W4X0X7BPJ) Inactive Ingre	rce) istration ient/Active ingra E ACETATE (UI edients	TOPICAL Moiety edient Name NII: 3X7931PO74) (HYDROCORTISON	IE -	HYDROCORTIS	ONE	1 g in 100 g
Item Code (Sour Route of Admini Active Ingredi HYDROCORTISON UNII: W4X0X7BPJ) Inactive Ingre GLYCERYL MONOS TROLAMINE (UNII:	rce) istration ient/Active ingra E ACETATE (UN edients STEARATE (UN 903K9353TK)	TOPICAL Moiety edient Name NII: 3X7931PO74) (HYDROCORTISON Ingredient Name II: 2300U9XXE4)	IE -	HYDROCORTIS	ONE	1 g in 100 g
Item Code (Sour Route of Admini Active Ingredi HYDROCORTISON UNII: W4X0X7BPJ) Inactive Ingre GLYCERYL MONOS TROLAMINE (UNII: DIAZOLIDINYL UR	rce) istration ient/Active ingra E ACETATE (UI edients STEARATE (UN 903K93S3TK) EA (UNII: H5RIZ	TOPICAL Moiety edient Name NII: 3X7931PO74) (HYDROCORTISON Ingredient Name II: 2300U9XXE4) BMPW4)	IE -	HYDROCORTIS	ONE	1 g in 100 g
Item Code (Sour Route of Admini Active Ingredi HYDROCORTISON UNII: W4X0X7BPJ) Inactive Ingre GLYCERYL MONOS TROLAMINE (UNII: DIAZOLIDINYL URE PROPYLPARABEN	rce) istration ient/Active ingre E ACETATE (UN edients STEARATE (UN 903K93S3TK) EA (UNII: H5RIZ (UNII: Z8IX2SC]	TOPICAL Moiety edient Name NII: 3X7931PO74) (HYDROCORTISON Ingredient Name II: 2300U9XXE4) BMPW4)		HYDROCORTIS	ONE	1 g in 100 g
Item Code (Sour Route of Admini Active Ingredi HYDROCORTISON UNII: W4X0X7BPJ)	rce) istration ient/Active ingro e ACETATE (UN edients STEARATE (UN 903K93S3TK) EA (UNII: H5RIZ (UNII: Z8IX2SCI 960K00R)	TOPICAL Moiety edient Name NII: 3X7931PO74) (HYDROCORTISON Ingredient Name II: 2300U9XXE4) BMPW4)	IE -	HYDROCORTIS	ONE	1 g in 100 g
Item Code (Sour Route of Admini Active Ingredi HYDROCORTISON UNII: W4X0X7BPJ) Inactive Ingre GLYCERYL MONOS TROLAMINE (UNII: DIAZOLIDINYL URE PROPYLPARABEN WATER (UNII: 059Q	rce) istration ent/Active ing ro e ACETATE (UN edients stearate (UN 903K93S3TK) EA (UNII: H5RIZ (UNII: Z8IX2SC) FOKOOR) DC6A3C0OX)	TOPICAL Moiety edient Name NII: 3X7931PO74) (HYDROCORTISON Ingredient Name I: 2300U9XXE4) I: 2300U9XXE4) I: OH)		HYDROCORTIS	ONE	1 g in 100 g
Item Code (Sour Route of Admini Active Ingredi HYDROCORTISON UNII: W4X0X7BPJ) Inactive Ingre GLYCERYL MONOS TROLAMINE (UNII: DIAZOLIDINYL URE PROPYLPARABEN WATER (UNII: 059Q GLYCERIN (UNII: PE	rce) istration ient/Active ingre E ACETATE (UN edients STEARATE (UN 903K93S3TK) EA (UNII: H5RIZ (UNII: Z8IX2SCI FOKOOR) DC6A3C0OX) OHYDRATE (UN	TOPICAL Moiety edient Name NII: 3X7931PO74) (HYDROCORTISON Ingredient Name II: 2300U9XXE4) BMPW4) LOH) NII: 2968PHW8QP)	IE -	HYDROCORTIS	ONE	1 g in 100 g

	THYLPARAE				
PRC	PYLENE G	LYCOL	(UNII: 6DC9Q167V3)		
EDE	TATE DISC	DIUM	(UNII: 7FLD91C86K)		
STE	ARIC ACID	(UNII: 4	ELV7Z65AP)		
Pa	ckaging				
#	ltem Code		Package Description	Marketing Start Date	Marketing End Date
1		0.9 g i Produc	n 1 PACKET; Type 0: Not a Combination		
Ma	arketin	ıg In	formation		
Ma	arketin Marketin Categor	g	formation Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
una	Marketin Categor	ig y	Application Number or Monograph		Marketing End Date
	Marketin Categor	ig y	Application Number or Monograph	Date	
una	Marketin Categor	ig y	Application Number or Monograph	Date	
una othe	Marketin Categor pproved dru er	ig у ј	Application Number or Monograph	Date	
una othe	Marketin Categor pproved dru er	ig ig ig ig In	Application Number or Monograph Citation	Date	Date
una othe Ma	Marketin Categor pproved dru er Arketin Marketin Categor pproved dru	ng y ig ig In ig y	Application Number or Monograph Citation formation Application Number or Monograph	Date 10/15/2019 Marketing Start	Date Marketing End

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

Revised: 1/2024

Honeywell Safety Products USA, Inc.