4398 FIRST AID KIT- 4398 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.

4398 First Aid Kit (Triple, alcohol wipes, EW, PAWS- 68200)

Triple Active ingredient

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

T riple *Purpose*

First aid antibiotic First aid antibiotic First aid antibiotic

Triple

Uses

first aid to help prevent infection in:

- minor cuts
- scrapes
- burns

T riple *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

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

Ask a doctor before use if you have

- a deep or puncture wounds
- animal bites

• serious burns

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

T riple Inactive ingredient

petrolatum

Triple

Questions?

1-800-430-5490

Eyewash Active ingredient

Sterile Water 99%

Eyewash

Purpose

Eyewash

Eyewash

Uses

• for flushing the eye to remove loose foreign material, air pollutants or chlorinated water

Eyewash *Warnings*

For external use only

- Obtain immediate medical treatment for all open wounds in or near eyes.
- To avoid contamination, do not touch tip of container to any surface.
- Do not reuse.

• Once opened, discard.

Do not use

- if solution changes color or becomes cloudy
- if you have open wounds in or near the eyes, get medical help right away.

Stop use and ask a doctor if

- you experience eye pain
- changes in vision
- continued redness or irritation of the eye
- condition worsens or persists

Keep out of reach of children

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

Eyewash

Directions

- remove contacts before using
- twist top to remove
- flush the affected area as needed
- control rate of flow by pressure on the bottle
- if necessary, continue flushing with emergency eyewash or shower

Eyewash Inactive ingredients

sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic

Eyewash

Questions

Call 1-800-430-5490 Honeywell Safety Products USA, Inc. Smithfield, RI 02917

PAWS Active ingredient

Ethyl alcohol 66.5%

PAWS

Purpose

Antiseptic

PAWS

Uses

• for handwashing to decrease bacteria on skin whenever soap and water is not readily available

PAWS Warnings

For external use only

Flammable: keep away from fire or flame

Do not use

• in the eyes. If this happens, rinse thoroughly with water.

Stop use and ask a doctor if

• irritation or redness develop and persists for more than 72 hours

Keep out of reach of children

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

PAWS

Directions

- wet hands and wrists thoroughly for 15 seconds and allow to air dry
- always reseal after use
- children under 6 years of age should be supervised when using this product

PAWS Inactive ingredients

aloe vera, fragrance, purified water, triethanolamine

Paws Questions

1-800-430-5490

Alcohol Wipe *Active ingredient*

Isopropyl alcohol 70%

Alcohol Wipe

Purpose

First aid antiseptic

Alcohol Wipe

Uses

• first aid to help prevent infection in minor cuts, scrapes, and burns

Alcohol Wipe Warnings

For external useonly

Flammable, keep away from fire or flame.

Do not use

in the 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 one 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 condition persists or gets worse

Alcohol Wipe

Directions

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

Alcohol Wipe

Other information

• store at room temperature 15 ° to 25 ° C (59 ° to 77 ° F)

Alcohol Wipe

Inactive ingredients

water

Alcohol Wipe

Questions?

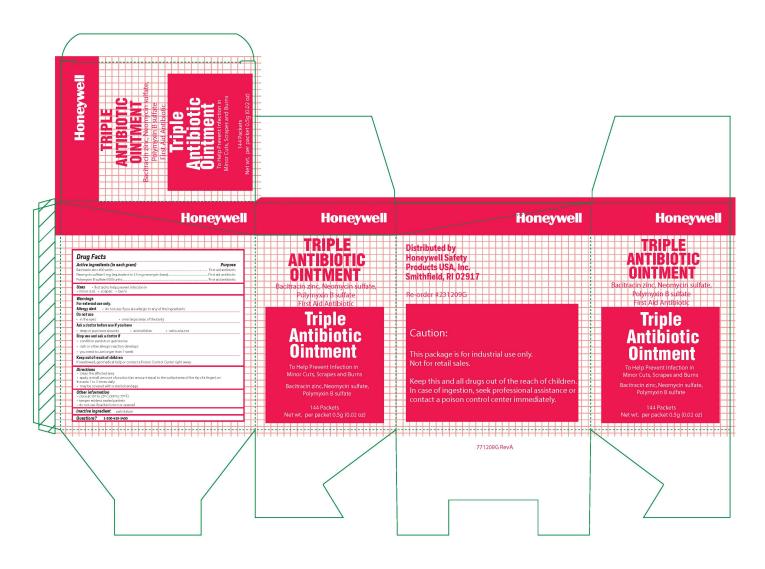
1-800-430-5490

4398 68200 Kit Contents

1 TRIPLE ANTIBIOTIC 10 PER 1 ALCOHOL PREP PADS 10P 1 ADHESIVE TAPE W/P 1/2"X10YDS 1 ADHESIVE TAPE W/P 1" X 10YDS 1 FIRST AID GUIDE ASHI

1 EMERGENCY SURVIVAL BLANKET 1 GAUZE CLEAN-WRAP BDGE N/S 3" 1 GAUZE CLEAN-WRAP BDGE N/S 4" **1 BLOODSTOPPER** 1 ABD COMBINE PAD 5" X 9" 1 ELASTIC BANDAGE 3" X 4.5YD **1 PAWS PERS ANTIMICRO WIPE** 1 4OZ BFS EYEWASH TRILINGUAL BOTTLE 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 2 TRI BNDG NON WOVEN 40"X40"X56" **4 EYE PADS STD OVAL STERILE** 10 GAUZE PADS 4"X4" 12PLY 1 POLYBAG 12" X 16" 3 MIL

Triple Antibiotic label



Eyewash



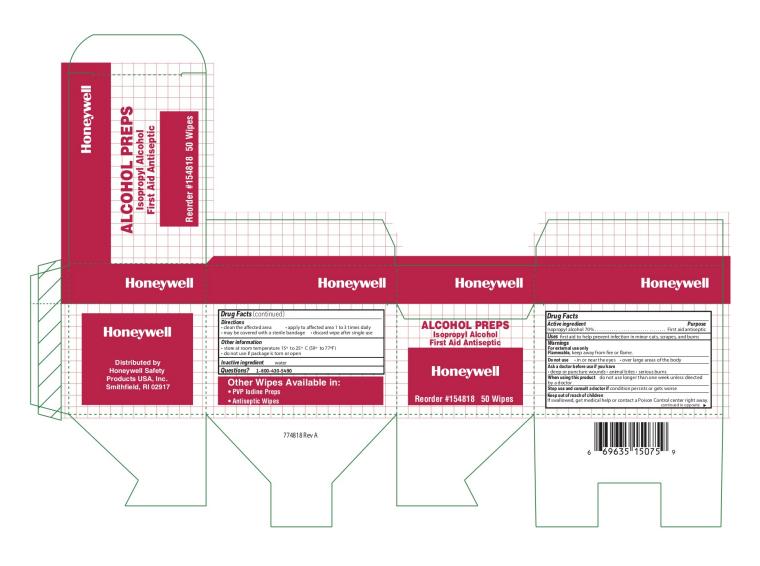
Datos de medicamento (Para EE ngrediente Activo	Propósito
gua estéril 99%	Lavaojos
/sos ara el lavado de ojo para quitar las particulas su os contaminantes aeros, o agua de cloruro	eltas y extrañas,
Advertencias	
ara el uso externo sólo - Obtenga tratamient mediato para todas las heridas abiertas en o ci ara evitar la contaminación, no toque la punta c inguna superficie. No vuelva a usar. Vez abierto	erca de los oios.
Io se use • si la solución se enturbia o cambi si tiene heridas abiertas en o cerca del ojo, obte e inmediato	
Deje de usar y consulte a un médico si: experimenta dolor de ojo • cambio de visiór rojez continuo o irritación del ojo la condición empeora o persiste	1
fanténgase fuera del alcance de los niños. In caso de ingestión accidental, obtenga atenció un Centro de control de envenenamiento inmed	
nstrucciones quitese los lentes de contacto antes de usar la tuerza la tapa para quitar enjuague el área afectada según se necesite controle el chorro haciendo presión el la botella si es necesario, sigue enjuagado con un lavaojos o d	a
ngredientes inactivos loruro de sodio, fosfato de sodio dibásico, fosfato de	e sodio monobásico
Preguntas? Llame al 1-800-430-5490	
oneywell Safety Products USA, Inc. Smithfield, I	RI. 02917
Information	
Information Usages	
Jsages Pour le rincage des yeux afin d'enlever un corps	étranger,
Usages Pour le rinçage des yeux afin d'enlever un corps les polluants atmospheriques où de l'eau chloré	étranger, ie .
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Jsages Your le rinçage des yeux afin d'enlever un corps les polluants atmospheriques où de l'eau chiore Advertissements Your usage externe seulement - Obtenir immé ions médicaux pour toutes les plaies ouvertes e uvert, jetez-terne seulement - obtenir immé ions médicaux pour toutes les plaies ouvertes e vert, seur ettre toute contamination, ne pas to écipient à n'importe quelle surface. Ne pas réut uvert, jetez-tes. Ve pas utiliser la solution a changé de couleur ou si elle est si vous avez des plaies ouvertes aux yeux ou à onsuluez immédiatement un médicain Desser d'utiliser la solution et consulter un n condition empire ou persiste Barder hors de la portée des enfants. En cas d'ingestion, communiquer immédiatemer u avec un centre antipoison. Mode d'emploi enlever les verres de contact avant l'utilisation houcins pour l'entever, in decuis avonte te la augmentant ou en réduisant la pression exerci- si necessaire, continuer de inner avec unesoli	e. diatement des diatement des dans ou près des ucher la pointe du liser. Une fois brouillée proximité, nédecin re vision change • dévisser le ée selton les solton les solton de micage n, phosphate

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PAWS label

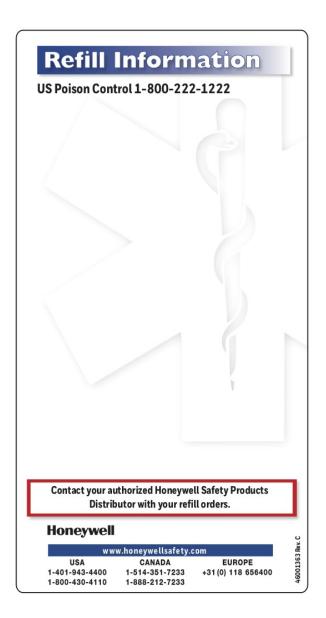


Alcohol Wipe Principal Display Panel



4398 kit label 68200

46001363 Rev.C Prints 3 colors Black, Red (PMS 186) and Blue (PMS 072)



Product Informatio	n			
Product T ype	HUMAN OTC DRUG	Item Code (Source)	ND	DC:0498-4398
Packaging				
# Item Code	Package Description	Marketing Start Da	ite M	arketing End Date
NDC:0498-4398-01	1 in 1 KIT	09/13/2018		
Quantity of Parts				
Part # Pa	ackage Quantity	Total P	Product Quar	ntity
Part 1 1 BOTTLE		118 mL		
Part 2 10 PACKET		9 g		
Part 3 10 POUCH		4 mL		
Part 4 1 PACKET		0.0019 L		
Part 1 of 4				
EYESALINE EM	IERGENCY EYEWA	SH		
EYESALINE EN purified water liquid		SH		
EYESALINE EN purified water liquid Product Informatio		SH		
EYESALINE EN purified water liquid Product Informatio Item Code (Source)	n NDC:0498-0100	SH		
EYESALINE EN purified water liquid Product Informatio Item Code (Source) Route of Administratio	n NDC:0498-0100 n OPHTHALMIC	SH		
EYESALINE EN purified water liquid Product Informatio Item Code (Source) Route of Administratio	n NDC:0498-0100 n OPHITHALMIC Active Moiety		Strongth	Strongth
EYESALINE EN purified water liquid Product Informatio Item Code (Source) Route of Administratio	n NDC:0498-0100 n OPHTHALMIC Active Moiety Ingredient Name	Basis of	Strength	Strength
EYESALINE EN purified water liquid Product Informatio Item Code (Source) Route of Administratio	n NDC:0498-0100 n OPHITHALMIC Active Moiety	Basis of	Strength	Strength 98.6 mL in 100 mL
EYESALINE EN purified water liquid Product Informatio Item Code (Source) Route of Administratio Active Ingredient/A	n NDC:0498-0100 n OPHTHALMIC Active Moiety Ingredient Name DOR) (WATER - UNII:059QF0K00F	Basis of	Strength	_
EYESALINE EN purified water liquid Product Informatio Item Code (Source) Route of Administratio Active Ingredient/A	n NDC:0498-0100 n OPHTHALMIC Active Moiety Ingredient Name DOR) (WATER - UNII:059QF0K00F	Basis of R) WATER	Strength	_
EYESALINE EN purified water liquid Product Informatio Item Code (Source) Route of Administratio Active Ingredient/A WATER (UNII: 059QF0KC	n NDC:0498-0100 n OPHTHALMIC	Basis of R) WATER	Strength	98.6 mL in 100 mL
EYESALINE EN purified water liquid Product Informatio Item Code (Source) Route of Administratio Active Ingredient/A WATER (UNII: 059QF0KC Inactive Ingredient	n NDC:0498-0100 n OPHTHALMIC Active Moiety Ingredient Name DOR) (WATER - UNII:059QF0K00F S Ingredient Name	Basis of WATER	Strength	98.6 mL in 100 mL
EYESALINE EN purified water liquid Product Informatio Item Code (Source) Route of Administratio Active Ingredient/A WATER (UNII: 059QF0KC Inactive Ingredients SO DIUM PHO SPHATE, E	n NDC:0498-0100 n OPHTHALMIC Active Moiety Ingredient Name DOR) (WATER - UNII:059QF0K00F S Ingredient DIBASIC (UNII: GR686LBA74) MONOBASIC, MONOHYDRATE (Basis of WATER	Strength	98.6 mL in 100 mL
EYESALINE EN purified water liquid Product Informatio Item Code (Source) Route of Administratio Active Ingredient/A WATER (UNII: 059QF0KC Inactive Ingredient: SO DIUM PHO SPHATE, E SO DIUM PHO SPHATE, E SO DIUM PHO SPHATE, I	n NDC:0498-0100 n OPHTHALMIC Active Moiety Ingredient Name DOR) (WATER - UNII:059QF0K00F S Ingredient DIBASIC (UNII: GR686LBA74) MONOBASIC, MONOHYDRATE (Basis of WATER	Strength	98.6 mL in 100 mL
EYESALINE EN purified water liquid Product Informatio Item Code (Source) Route of Administratio Active Ingredient/A WATER (UNII: 059QF0KC Inactive Ingredients SO DIUM PHO SPHATE, E	n NDC:0498-0100 n OPHTHALMIC Active Moiety Ingredient Name DOR) (WATER - UNII:059QF0K00F S Ingredient DIBASIC (UNII: GR686LBA74) MONOBASIC, MONOHYDRATE (Basis of R) WATER : Name UNII: 593YOG76RN)		98.6 mL in 100 mL

Marketing Info	rmation						
Marketing Category	Applicatio	on Number or Monog	raph Citation	Marketi	ng Start Date	Mark	eting End Dat
OTC monograph final	part349			12/18/2018			
Part 2 of 4							
TRIPLE ANTI bacitracin zinc, polyr		te, neomycin sulfate	ointment				
Product Informati	on						
Item Code (Source)	011	NDC:0498-0750					
Route of Administrati	ion	TOPICAL					
Active Ingredient/	Active Moi	ety					
	Ing	redient Name			Basis of Stre	ngth	Strength
POLYMYXIN B SULFA	TE (UNII: 1937	1312D4) (POLYMYXIN I	3 - UNII:J2VZ07J9	6K)	POLYMYXIN B		5000 [iU] in 1
BACITRACIN ZINC (UN	√II: 89Y4M234E	S) (BACITRACIN - UNI	I:58 H6 RWO 52 I)		BACITRACIN		400 [iU] in 1 g
NEO MYCIN SULFATE ((UNII: 057¥626	693) (NEOMYCIN - UN	III:116QD7X297)		NEOMYCIN		3.5 mg in 1 g
Inactive Ingredien	nts						
		Ingredient Name				Str	ength
PETROLATUM (UNII: 4	T6 H12 B N9 U)						
Product Characte	ristics						
Color	10 1100	white	Score				
Shape			Size				
Flavor							
			Imprint Code				
			Imprint Code				
Contains			Imprint Code				
Contains Packaging		Package Descriptio		Marketi	ng Start Date	Marke	ting End Dat
Contains Packaging		• •	on	Marketi	ng Start Date	Marke	eting End Dat
Contains Packaging # Item Code 1 NDC:0498-0750-35	0.9 g in 1 PACK	• •	on	Marketi	ng Start Date	Marke	ting End Da
Contains Packaging # Item Code 1 NDC:0498-0750-35	0.9 g in 1 PACK rmation	• •	n Ibination Product		ng Start Date ng Start Date		
Contains Packaging # Item Code 1 NDC:0498-0750-35 Marketing Info Marketing Category	0.9 g in 1 PACK rmation	KET; Type 0: Not a Com	n Ibination Product		ng Start Date		
Contains Packaging # Item Code 1 NDC:0498-0750-35	0.9 g in 1 PACK P rmation Applicatio	KET; Type 0: Not a Com	n Ibination Product	Marketi	ng Start Date		eting End Dat

Part 3 of 4 **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 -ISOPROPYL 0.7 mL in 1 mL UNII:ND2M416302) ALCOHOL **Inactive Ingredients Ingredient Name** Strength WATER (UNII: 059QF0KO0R) Packaging Item Code Marketing Start Date Marketing End Date # **Package Description** 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 OTC monograph not final part333A 09/18/2018 Part 4 of 4 **PAWS** ethyl alcohol liquid **Product Information** Item Code (Source) NDC:0498-3111 **Route of Administration** TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength

ALCOHOL

macuve mg	re die nts			
		Ingredient Name		Strength
TROLAMINE (U	JNII: 903K	93S3TK)		
ALOE VERA LE	AF (UNII: 2	ZY81Z83H0X)		
WATER (UNII: 0	59QF0KO	0 R)		
Packaging				
# Item Code		Package Description	Marketing Start Date	Marketing End Date
1	0.0019 L	in 1 PACKET; Type 0: Not a Combination Product		
1	0.0019 L	in 1 PACKET; Type 0: Not a Combination Product		
1				
	Infor		Marketing Start Date	Marketing End Date
Marketing Marketing Ca	Infori ategory	mation	Marketing Start Date	Marketing End Date
Marketing	Infori ategory	mation Application Number or Monograph Citation	C C	Marketing End Date
Marketing Marketing Ca	Infori ategory	mation Application Number or Monograph Citation	C C	Marketing End Date
Marketing Marketing Ca	g Infor ı ategory not final	mation Application Number or Monograph Citation part333E	0	Marketing End Date
Marketing Marketing Ca OTC monograph	inform ategory not final	mation Application Number or Monograph Citation part333E	0	Marketing End Date Marketing End Date

Labeler - Honeywell Safety Products USA, Inc. (079287321)

Registrant - Honeywell Safety Products USA, Inc. (079287321)

Establishment

Name	Address	ID/FEI	Business Operations
Honeywell Safety Products USA, Inc		079287321	pack(0498-4398)

Establishment

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

Establishment

Name	Address	ID/FEI	Business Operations
Honeywell Safety Products USA, Inc.		167518617	manufacture(0498-0100)

Establishment

Name	Address	ID/FEI	Business Operations
Changzhou Maokang Medical		421317073	manufacture(0498-0143)

Establishment						
Name	Address	ID/FEI	Business Operations			
Safetec of America Inc		874965262	manufacture(0498-3111)			

Revised: 9/2019

Honeywell Safety Products USA, Inc.