ITCH AND BITE RELIEF FIRST AID KIT- hydrocortisone and diphenhydramine
ITCH AND BITE RELIEF FIRST AID KIT- hydrocortisone and diphenhydramine hydrochloride
WAL-MART STORES, INC.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Itch and Bite Relief First Aid Kit

Active ingredient **(Hydrocortisone Cream)**

Hydrocortisone 1.0%

Purpose**(Hydrocortisone Cream)**

Anti-itch

Uses **(Hydrocortisone cream)**

• For temporary relief of itching associated with minor skin irritations, inflammation, or rashes due to:

• eczemas

• insect bites

• poison ivy, oak or sumac

• soaps

• detergents

• cosmetics

• jewelry

• seborrheic dermatitis

• psoriasis

• Other uses of product should be only under the advice and supervision of a doctor.

Warnings**(Hydrocortisone Cream)**

For external use only

Do not use (Hydrocortisone cream)

• in the eyes

• for treatment of diaper rash

• for feminine itching

Ask a doctor before use if you are (Hydrocortisone cream)

• using any other hydrocortisone product

Stop use and ask a doctor if (Hydrocortisone cream)

the condition worsens or lasts more than 7 days, or clears up and occurs again within a few days

Keep out of reach of children (Hydrocortisone cream)

If ingested, contact a Poison Control Center right away

Directions **(Hydrocortisone cream)**

• Apply to affected area not more than 3 to 4 times daily

• Children under 2: ask a doctor

Other information **(Hydrocortisone cream)**

• Store at room temperature (do not freeze)

• Do not use any opened or torn packets

Inactive ingredients**(Hydrocortisone cream)**

emulsifying wax, ethanol, methylparaben, mineral oil, paraffin, petrolatum, propylparaben, purified water, white wax

Active ingredient (in each caplet)**(Diphen caplet)**

Diphenhydramine Hydrochloride 25 mg

Uses **(Diphen caplet)**

Temporarily relieves these symptoms due to hay fever or other respiratory allergies

• runny nose • sneezing • itching of the nose or throat • itchy, watery eyes

Temporarily relieves these symptoms due to the common cold

• runny nose • sneezing

Warnings **(Diphen caplet)**

Do not use

• to make children sleepy

• with any other product containing diphenhydramine, even one that is used on skin.

Ask a doctor before use if you have (Diphen caplet)

• a breathing problem such as emphysema or chronic bronchitis
• difficulty in urination due to enlargement of the prostate gland
• glaucoma

When using this product (Diphen caplet)

• marked drowsiness may occur
• avoid alcohol beverages
• alcohol, sedatives and tranquilizers may increase the drowsiness effect
• use caution when driving a motor vehicle or operating machinery
• excitability may occur, especially in children

If pregnant or breast-feeding (Diphen caplet)

ask a health care professional before use.

Keep out of reach of children (Diphen caplet)

n case of overdose, contact a physician or poison control center immediately.

Directions **(Diphen caplet)**

• do not take more than directed

Adults and children (12 years and older): Take 1 to 2 caplets every 4 to 6 hours as needed. Do not take more than 12 caplets in 24 hours, or as directed by a doctor.

Children under 12 years: Do not give to children under 12 years of age.

Other information **(Diphen caplet)**

• each caplet may contain: calcium 25mg
• store at room temperature 59º to 86ºF (15º to 30ºC)
• protect from light
• use by expiration date on packet
• tamper-evident sealed packetsM
• do not use any opened or torn packets

Inactive ingredients **(Diphen caplet)**

carnauba wax*, colloidal silicon dioxide, croscarmellose sodium, D&C red #27, dicalcium

phosphate*, hypromellose, lactose*, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate*, titanium dioxide

* *may contain*

First Aid Kit Package/Label Principal Display Panel

OZARK TRAIL

OUTDOOR EQUIPMENT

ITCH & BITE RELIEF

FIRST AID KIT

- Ideal for minor insects bites and itches

9 PIECES

SEE BACK PANEL FOR KIT CONTENTS

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ITCH AND BITE RELIEF FIRST AID KIT

hydrocortisone and diphenhydramine kit

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49035-057

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-057-09	1 in 1 CASE; Type 0: Not a Combination Product	09/09/2020	03/12/2025

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	4 POUCH	3.6 g
Part 2	4 PACKET	4

Part 1 of 2

HYDROCORTISONE

hydrocortisone cream

Product Information	
Item Code (Source)	NDC:61010-5800
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	10 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8C7HI9T)	
WATER (UNII: 059QF0KO0R)	
MINERAL OIL (UNII: T5L8T28FGP)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
STEARETH-20 (UNII: L0Q8IK9E08)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61010-5800-1	0.9 g 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	part348		

Part 2 of 2

MEDIQUE DIPHEN

diphenhydramine hydrochloride tablet, film coated

Product Information

Item Code (Source)	NDC:47682-167
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
LACTOSE (UNII: J2B2A4N98G)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	pink (pink)	**Score**	no score
Shape	OVAL (oval)	**Size**	11mm
Flavor		**Imprint Code**	048;D
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47682-167-46	1 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 final	part341		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part348	09/09/2020	03/12/2025

ITCH AND BITE RELIEF FIRST AID KIT

hydrocortisone and diphenhydramine hydrochloride kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49035-588

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-588-09	1 in 1 CASE; Type 0: Not a Combination Product	10/30/2019	03/12/2025

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	4 POUCH	3.6 g
Part 2	4 PACKET	4

Part 1 of 2

HYDROCORTISONE

hydrocortisone cream

Product Information	
Item Code (Source)	NDC:61010-5800
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	10 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
STEARETH-20 (UNII: L0Q8IK9E08)	
ALCOHOL (UNII: 3K9958V90M)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0KO0R)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
MINERAL OIL (UNII: T5L8T28FGP)	
PARAFFIN (UNII: I9O0E3H2ZE)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:61010-5800-1	0.9 g 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	part348		

Part 2 of 2

MEDIQUE DIPHEN

diphenhydramine hydrochloride tablet, film coated

Product Information	
Item Code (Source)	NDC:47682-184

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

Product Characteristics

Color	pink (pink)	**Score**	no score
Shape	OVAL (oval)	**Size**	11mm
Flavor		**Imprint Code**	061;T
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47682-184-46	1 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 final	part341		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/30/2019	03/12/2025

Labeler - WAL-MART STORES, INC. (051957769)

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