ITCH RELIEF- diphenhydramine hydrochloride liquid Safetec of America, Inc.

61010-8300, Itch Relief Spray

Drug Facts

Active Ingredients

Diphenhydramine hydrochloride 2%

Purpose

External Analgesic

Uses:

For the temporary relief of pain and itching associated with minor skin irritations and rashes due to insect bites, poison oak and poison sumac.

Warnings

For external use only

Do not use

- on large areas of the body
- with any other products using diphenhydramine hydrochloride, even one taken by mouth

Ask a doctor before use

- on chicken pox
- on measles

When using this product

avoid contact with the eyes

Stop use and ask doctor if

- condition worsens
- symptoms persist more than 7 days or clear up and occur again within a few days

Keep out of reach of childrenIf swallowed, get medical help or contact a poison control center right away.

Directions:

- 12 and over: apply to affected area not more than 3 to 4 times daily
- under 12: consult a doctor

Inactive Ingredients:

Germaben II, edetate disodium, glycerin, tomadol 25-9, purified water, triethanolamine

PRINCIPAL DISPLAY PANEL

NDC 61010-8300-1

Safetec

Diphenhydramine

Itch Relief Spray

Relief from pain and

itching due to insect

bites and rashes from

poison ivy, poison oak

and poison sumac.

Manufactured by

SAFETEC OF AMERICA, Inc.

Buffalo, NY 14215 800-456-7077

www.safetec.com

2 fl. oz. (59.1ml) Reorder no. 57001



Drug Facts

Active Ingredients

Purpose

Diphenhydramine hydrochloride 2%. External analgesic

Uses For the tepmorary relief of pain and itching associated with minor skin irritations and rashes due to insect bites, poison oak and poison sumac.

Warnings For external use only.

Do not use ■ on large areas of the body ■ with any other products using diphenhydramine hydrochloride, even one taken by mouth

Ask a doctor before use ■ on chicken pox ■ on measles

When using this product ■ avoid contact with the eyes

Stop use and ask doctor if ■ condition worsens ■ symptoms persist 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.

Directions ■ 12 and over: apply to affected area not more than 3 to 4 times daily ■ under 12: consult a doctor

Inactive Ingredients germaben II, edetate disodium, glycerin, tomadol 25-9, purified water, triethanolamine

ITCH RELIEF

diphenhydramine hydrochloride liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:61010-8300

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40)DIPHENHYDRAMINE (UNII: BGTS82S83M)DIPHENHYDRAMINE (UNII: BGTS82S83M)20.3 g (UNII: BGTS82S83M)

Inactive Ingredients

Ingredient Name	Strength
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	

GLYCERIN (UNII: PDC6A3C0OX)

C12-15 PARETH-9 (UNII: H3ZIY6WP1R)

EDETATE DISODIUM (UNII: 7FLD91C86K)

WATER (UNII: 059QF0KO0R)
TROLAMINE (UNII: 903K93S3TK)

# Item Code Package Description Marketing Start Date Marketing End Date 1 NDC:61010- 8300-1 0.0591 L in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product 05/02/2013	Packaging					
	#	Item Code	Package Description			
	1			05/02/2013		

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC Monograph Drug	M017	05/02/2013				

Labeler - Safetec of America, Inc. (874965262)

Establishment					
Name	Address	ID/FEI	Business Operations		
Safetec of America, Inc.		874965262	manufacture(61010-8300)		

Revised: 2/2024 Safetec of America, Inc.