IVAREST- zinc oxide, benzyl alcohol, and diphenhydramine hydrochloride cream Blistex 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.

Ivares t_®

Drug Facts

Active ingredients	Purpose
Calamine 14.0 % (w/w)	Skin protectant
Benzyl Alcohol 10.5 % (w/w)	External
Delizyi / Heolioi 10.5 /0 (w/w)	analgesic
Diphenhydramine Hydrochloride 2.0 % (w/w)	External
Diphenifydranine ffydrochiofide 2.0 % (w/w)	analgesic

Uses

- for the temporary relief of pain and itching associated with poison ivy, poison oak, poison sumac, insect bites or minor skin irritations.
- dries the oozing and weeping of poison:
 - ivy
 - oak
 - sumac

Warnings

For external use only

Do not use

- on large areas of the body
- with any other product containing diphenhydramine, even one taken by mouth

Ask a doctor before use

- on chicken pox
- on measles

When using this product

• do not get into eyes.

Stop use and ask a doctor if

- condition worsens
- symptoms last 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

- do not use more often than directed
- as soon as possible after exposure, wash affected area with soap and water (or Ivarest Poison Ivy Cleansing Foam). Gently pat dry.

- apply Ivarest liberally to form a layer you can not see through.
- adults and children 2 years and older: apply to affected area not more than 3 to 4 times daily. Children under 2 years of age: consult a doctor.

Other information

Avoid contact with clothing. Ivarest may stain certain fabrics.

Inactive ingredients

bentonite, benzethonium chloride, camphor, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, hydroxyethylcellulose, lanolin alcohol, lanolin oil, magnesium aluminum silicate, menthol, petrolatum, PEG-4, polyglyceryl-3 diisostearate, polysorbate 60, propylene glycol, purified water, PVP, red 33, sorbitan stearate, squalane, yellow 5, yellow 6

PRINCIPAL DISPLAY PANEL - 56g Tube Carton

2 Itch Relievers

NDC 10157-9077-1

MAXIMUM STRENGTH
IVAREST®
EXTERNAL ANALGESIC/
POISON IVY, OAK, SUMAC DRYING CREAM

POISON IVY ITCH RELIEF

8 Hour Relief

MEDICATED ANTI-ITCH CREAM

Double Relief Formula

1 Antihis tamine helps stop the reaction

2 Analgesic soothes itch fast

PLUS Skin protectant to help dry the rash

Poison Ivy, Oak & Sumac, Insect Bites, Minor Skin Irritations

NET WT 2 OZ(56g)

MAXIMUM STRENGTH

Double Relief Formula

2 Itch Relievers

NDC 10157-9077-1



EXTERNAL ANALGESIC/ POISON IVY, OAK, SUMAC DRYING CREAM

POISON IVY ITCH RELI

MEDICATED ANTI-ITCH CREAM



Double Relief Formula

VAREST.

- 1 Antihistamine helps stop the reaction
- 2 Analgesic soothes itch fast
- PLUS Skin protectant to help dry the rash



Antihistamine helps stop the reaction **Analgesic** soothes itch fast

PLUS Skin protectant to help dry the rash

Poison Ivy, Oak & Sumac, Insect Bites, Minor Skin Irritations

NET WT 2 OZ/56a)



MAXIMUM STRENGTH

Ivarest's unique double relief formula:

- Delivers fast relief for up to 8 hours from pain and itching caused by:
 - · Poison Ivv. Oak & Sumac
 - Insect Bites
 - Minor Skin Irritations
- Features tone-neutral protective coating.

C2012 Blistex Inc. P.O. Box 5392
Oak Brook, L 60522-5392
Blistex

(A) Carton is 100% Recyclable.





MAXIMUM STRENGTH

warest contains trusted, effective ingredients to relieve itching & discomfort for up to 8 hours, while helping to dry the rash.

- 1) Antihistamine helps stop the reaction
- 2 Analgesic soothes itch fast

PLUS Skin protectant to help dry the rash

Drug Facts

Active ingredients

Calamine 14.0 % (w/w) Benzyl Alcohol 10.5 % (w/w) Diphenhydramine Hydrochloride 2.0 % (w/w) Purpose

Skin protectant External analgesic External analgesic

Uses

- for the temporary relief of pain and itching associated with poison ivy, poison oak, poison sumac, insect bites or minor skin irritations.
- dries the oozing and weeping of poison: · ivy · oak · sumac

Wamings

For external use only

Do not use on large areas of the body with any other product containing diphenhydramine, even one taken by mouth

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

When using this product • do not get into eyes.

Stop use and ask a doctor if · condition worsens · symptoms last 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

- do not use more often than directed
- as soon as possible after exposure, wash affected area with soap and water (or Ivarest Poison by Cleansing Foam). Gently pat dry.
- apply Ivarest liberally to form a layer you can not see through. adults and children 2 years and older: apply to affected area not more than 3 to 4 times daily. Children under 2 years of age: consult a doctor.

Other information

Avoid contact with clothing, Ivarest may stain certain fabrics.

Inactive ingredients

bentonite, benzethonium chloride, camphor, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, hydroxyethylcellulose, lanolin alcohol, lanolin oil, magnesium aluminum silicate, menthol, petrolatum, PEG-4, polyglyceryl-3 diisostearate, polysorbate 60, propylene glycol, purified water, PVP, red 33, sorbitan stearate, squalane, yellow 5, yellow 6







IVAREST

zinc oxide, benzyl alcohol, and diphenhydramine hydrochloride cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:10157-9077

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	14 g in 100 g	
Benzyl Alcohol (UNII: LKG8494WBH) (Benzyl Alcohol - UNII:LKG8494WBH)	Benzyl Alcohol	10.5 g in 100 g	
Diphenhydramine Hydrochloride (UNII: TC2D6JAD40) (Diphenhydramine - UNII:8GTS82S83M)	Diphenhydramine Hydrochloride	2 g in 100 g	

Inactive Ingredients	
Ingredient Name	Strength
bentonite (UNII: A3N5ZCN45C)	
benzethonium chloride (UNII: PH41D05744)	
lanolin alcohols (UNII: 884C3FA9HE)	
lanolin oil (UNII: OVV5IIJ58F)	
magnesium aluminum silicate (UNII: 6M3P64V0NC)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
petrolatum (UNII: 4T6H12BN9U)	
polyethylene glycol 200 (UNII: R95B8J264J)	
polyglyceryl-3 diisostearate (UNII: 46 P231IQV8)	
polysorbate 60 (UNII: CAL22UVI4M)	
propylene glycol (UNII: 6DC9Q167V3)	
water (UNII: 059QF0KO0R)	
D&C red no. 33 (UNII: 9DBA0SBB0L)	
sorbitan monostearate (UNII: NVZ4I0H58X)	
squalane (UNII: GW89575KF9)	
FD&C yellow no. 5 (UNII: I753WB2F1M)	
FD&C yellow no. 6 (UNII: H77VEI93A8)	
camphor (synthetic) (UNII: 5TJD82A1ET)	
povidone-iodine (UNII: 85H0 HZU99M)	
HYDRO XYETHYL ACRYLATE/SODIUM ACRYLO YLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)	

Product	Characteristics
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Color WHITE Score

Shape	Size	
Flavor	Imprint Code	
Contains		

	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:10157-9077-1	1 in 1 CARTON	12/31/2007	
	1	56 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part347	12/31/2007	

Labeler - Blistex Inc (005126354)

Establishment			
Name	Address	ID/FEI	Business Operations
Blistex Inc		005126354	MANUFACTURE(10157-9077)

Revised: 12/2019 Blistex Inc