

ARMAND REGULAR STRENGTH ITCH STOPPING- diphenhydramine hydrochloride, zinc acetate cream

Weeks & Leo

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.

Armand Regular Strength Itch Stopping Cream Drug Facts

Active Ingredients

Diphenhydramine hydrochloride 2%

Zinc acetate 0.1%

Purpose

Diphenhydramine hydrochloride.....Topical anagesic

Zinc acetate.....Skin protectant

Uses

temporarily relieves pain and itching due to:

- insect bites
- minor burns
- sunburn
- minor skin irritations
- minor cuts
- scrapes
- rashes due to poison ivy, poison oak, and poison sumac

dries the oozing and weeping due to 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
- adults and children 2 years and older: apply to affected area not more than 3 to 4 times daily
- children under 2 years: ask a doctor

Other Information

- store at 20° C to 25° C (68° F to 77° F)

Inactive Ingredients

cetyl alcohol, diazolidinyl urea, glyceryl stearate, methylparaben, PEG-40 stearate, PEG-100 stearate, propylene glycol, propylparaben, purified water

Package Label

Armand REGULAR STRENGTH ITCH Itch relief CREAM

Relieves pain from insects bites & skin irritation

Topical Analgesic

Skin Protectant

Regular strength ITCH Itch relief CREAM

compare to the active ingredients in Benadryl ® Original strength itch stopping cream

Relieves Pain & Itch fast

Itch stopping Cream



ARMAND REGULAR STRENGTH ITCH STOPPING

diphenhydramine hydrochloride, zinc acetate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11383-261
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	10 mg in 1 g
ZINC ACETATE (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	1 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
WATER (UNII: 059QF0K00R)	

PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11383-261-51	1 in 1 CARTON	03/17/2014	
1		28 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 not final	part348	03/17/2014		

Labeler - Weeks & Leo (005290028)

Registrant - Weeks & Leo Co., Inc. (005290028)

Establishment			
Name	Address	ID/FEI	Business Operations
Weeks & Leo Co., Inc.		005290028	manufacture(11383-261)

Revised: 4/2019

Weeks & Leo