BITE AND ITCH- diphenhydramine hydrochloride, pramoxine hydrochloride lotion
Weeks & Leo Co., Inc.

Bite and Itch Lotion

Active ingredients

Diphenhydramine HCl 2%

Pramoxine HCl 1%

Purposes

Topical analgesic

Topical analgesic

Uses

Temporarily relieves pain and itching due to:
- scrapes
- sunburn
- minor cuts
- minor burns
- insect bites
- minor skin irritations
- poison ivy, poison oak, or poison sumac

Directions
- do not use more often than directed
- adults and children 12 years and over: apply to affected area not more than 3 to 4 times daily
- children under 12 years: ask a doctor

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 if you have
- **chicken pox**
- **measles**

When using this product do not get into eyes

Stop use and ask a doctor if
- **condition gets worse**
- **symptoms last for 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.

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- chicken pox
- measles

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Other information

- store at controlled room temperature
- call (515) 276-1586 to report any side effects that may occur

Inactive ingredients

cetyl alcohol, diazolidinyl urea, glyceryl stearate, isopropyl myristate, menthol, methylparaben, PEG-100 stearate, polyoxyl 40 stearate, propylene glycol, propylparaben, purified water, stearyl alcohol

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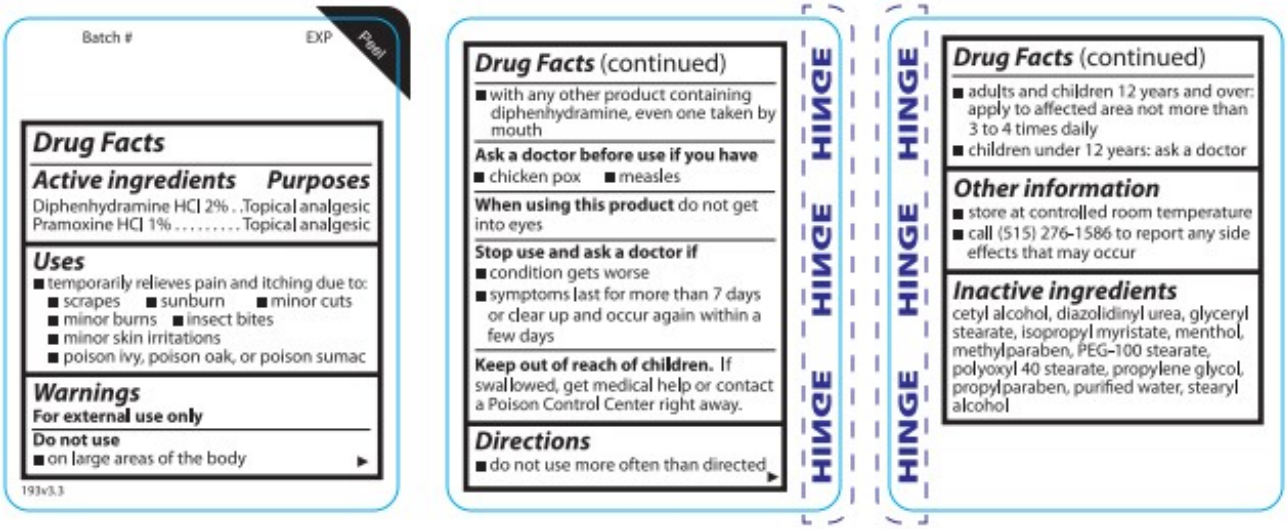

Bite and Itch

Lotion

Pramoxine HCl 1%

Topical Anesthetic

Diphenhydramine HCl 2%

Antihistamine

Pain Relieving Lotion

4 Fl Oz (118 mL)

BITE AND ITCH

diphenhydramine hydrochloride, pramoxine hydrochloride lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11383-192
Route of Administration	CUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	1 g in 100 mL
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	2 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
MENTHOL (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
WATER (UNII: 059QF0KO0R)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
GLYCERYL STEARATE/PEG-100 STEARATE (UNII: RD25J5V947)	
PEG-40 GLYCERYL STEARATE (UNII: 0A0VSM3HAD)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Product Characteristics			
Color	white (White to off-white)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11383-192-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/15/2015	
2	NDC:11383-192-01	1 in 1 CARTON	06/15/2015	
2		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	06/15/2015	

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

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

Establishment

Name	Address	ID/FEI	Business Operations
Weeks & Leo Co., Inc.		005290028	manufacture(11383-192)

Revised: 12/2024 Weeks & Leo Co., Inc.