SELECT BRAND EXTRA STRENGTH ITCH STOPPING- diphenhydramine hydrochloride gel
Select Brand

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.

Extra Strength

SELECT BRAND ITCH STOPPING GEL

Drug Facts

Active ingredient

Diphenhydramine HCl 2%

Purpose

Topical analgesic

Uses

- temporarily relieves pain and itching associated with:
  - insect bites
  - minor burns
  - sunburn
  - minor skin irritations
  - minor cuts
  - scrapes
  - rashes due to poison ivy, poison oak, and poison 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 persist 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.

Directions

- do not use more than directed
- adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily
- children under 2 years of age: ask a doctor

Other information

- store at 20 ºC to 25 ºC (68 ºF to 77 ºF)

Inactive ingredients

camphor, citric acid, diazolidinyl urea, hypromellose, methylparaben, propylene glycol, propylparaben, purified water, SD alcohol 40-B, sodium citrate

Distributed by:

SELECT BRAND DISTRIBUTORS

Pine Bluff, AR 71603 USA

AC (870) 535-3635

FOR SKIN USE ONLY

SELECT BRAND

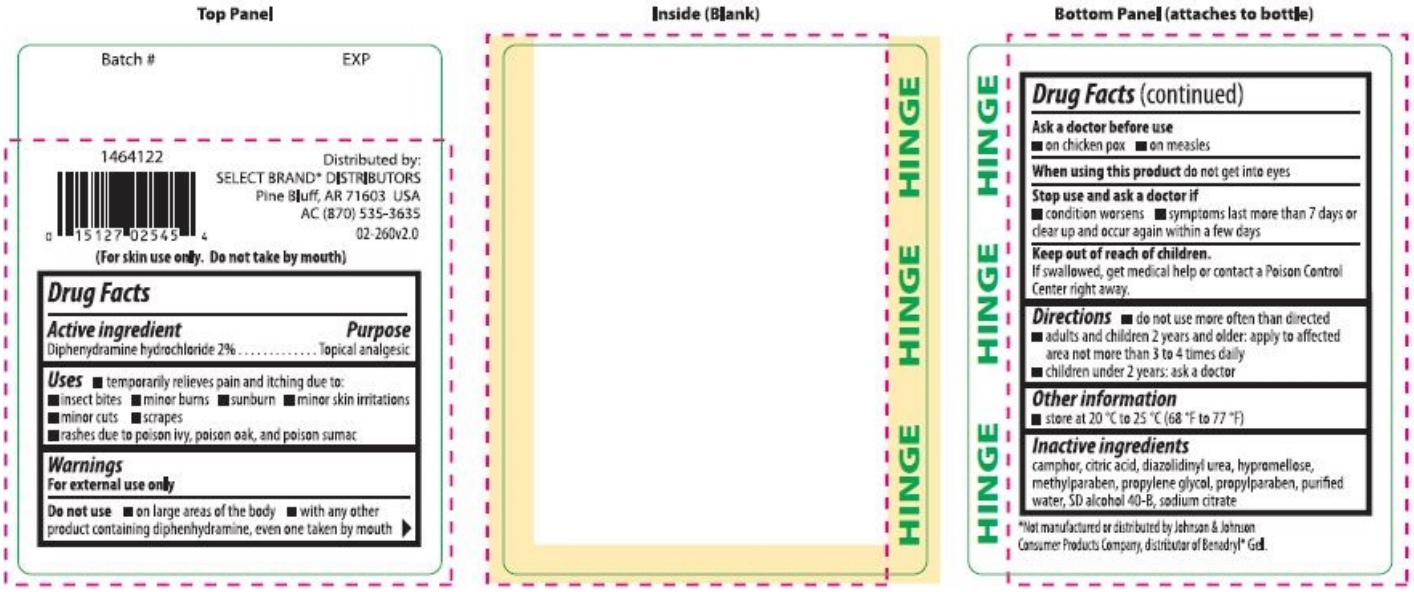
Topical Analgesic

ITCH STOPPING GEL

EXTRA STRENGTH

Diphenhydramine Hydrochloride 2%

4 FL OZ (118mL)



SELECT BRAND EXTRA STRENGTH ITCH STOPPING

diphenhydramine hydrochloride gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:15127-055
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	.2 g in 10 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
ALCOHOL (UNII: 3K9958V90M)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:15127-055-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/11/2012	

Labeler - Select Brand (043562370)

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

Establishment

Name	Address	ID/FEI	Business Operations
Weeks & Leo Co., Inc.		005290028	manufacture(15127-055)

Revised: 1/2015

Select Brand