

**HENRY SCHEIN FLEXIBLE UNNA BOOT WITH CALAMINE - zinc oxide,
calamine dressing
Henry Schein, 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.

Drug Facts

Active Ingredients

Zinc Oxide 25%, Calamine 1%

Purpose

Skin Protectant

Uses

- Dries the oozing and weeping of poison ivy, poison oak, or poison sumac.
- Ideal for managing extremities (e.g., varicose ulcers) requiring protection and support.

Warning

For external use only.

Avoid contact with eyes.

Ask a doctor

If condition worsens or does not improve within 7 days, consult a doctor

Keep out of reach of children

Keep this and all medicines out of children's reach.

Direction

- Begin bandaging at base of toes, without pressure, keeping foot and leg at right angle. Continue bandaging beyond ankle, doubling back to ensure molding to contours of leg (STEP 1)
- Complete bandaging to just below the knees (STEP 2).
- Apply an elastic adhesive bandage (STEP 3).

Other Ingredients

Acacia, Castor oil, Glycerin, and White Petrolatum.

Principal Display Panel

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0404-0011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	25.985 g
FERRIC OXIDE RED (UNII: 1K09F3G675) (FERRIC OXIDE RED - UNII:1K09F3G675)	FERRIC OXIDE RED	0.015 g

Inactive Ingredients	
Ingredient Name	Strength
ACACIA (UNII: 5C5403N26O)	
CASTOR OIL (UNII: D5340Y2I9G)	
GLYCERIN (UNII: PDC6A3C0OX)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0404-0011-04	1 in 1 BOX; Type 0: Not a Combination Product	07/27/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	07/27/2016	

Labeler - Henry Schein, Inc. (012430880)

Establishment			
Name	Address	ID/FEI	Business Operations
Laboratorios Le Roy		588387394	manufacture(0404-0011)

Revised: 7/2016

Henry Schein, Inc.