

**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

NDC 0404-0010-03

HENRYSCHEIN

MEDICAL BANDAGE

A Flexible Unna Boot With Calamine

BOTA DE UNNA FLEXIBLE CON CALAMINA

Venda Cola de Zinc Cierre con tira de gasa








BOTTE D'UNNA FLEXIBLE AVEC CALAMINE

Bande Unna elastique Gaze tissee

REF 900-7455

Bandage Size/Tamaño/Format du pansement/ Bandagengroße/Misura della fascia:

3" X 10 Yds. (7.6 cm X 9 meters)

<p> HENRY SCHEIN® MEDICAL BANDAGE</p> <p><i>A Flexible Unna Boot With Calamine</i></p> <p>An impregnated gauze bandage containing zinc oxide, glycerin and calamine. Vendaje de gasa impregnada con óxido de zinc, glicerina y calamina. Bande de gaze imprégnée contenant de l'oxyde de zinc, de la glycérine et de la calamine.</p> <p>Store at room temperature Conservar a temperatura ambiente Conservier à température ambiante</p> <p>Distributed by (in US only): HENRY SCHEIN INC, 135 DURYEA ROAD, MELVILLE, NY 11747 USA</p> <p>Made in Mexico Fabricado en Mexico Fabriqué au Mexique/</p>	<p> HENRY SCHEIN® MEDICAL BANDAGE</p> <p>Directions For Use/Modo de empleo/Mode d'emploi</p> <p>Step: 1/Passo: 1/1ère étape:  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. Llegado el vendaje a la base de los dedos, sin presión, mantenga el pie y pierna en un ángulo adecuado. Continúe vendando más allá del tobillo, plegando por detrás para asegurar la adaptación al contorno de la pierna. Bander la cheville en commençant par les orteils, sans pression, et en maintenant le pied à angle droit. Continuez au-delà de la cheville, en revenant en arrière de manière à bien mouler la jambe.</p> <p>Step: 2/Passo: 2/2ème étape:  Complete bandaging to just below the knee. Vende justo por debajo de la rodilla. Monter jusqu'au bas du genou.</p> <p>Step: 3/Passo: 3/3ème étape:  Apply elastic adhesive bandage. Aplique venda elástica adhesiva. Appliquez le pansement adhésif.</p>	<p>NDC# 0404-0010-03</p> <p> HENRY SCHEIN® MEDICAL BANDAGE</p> <p><i>A Flexible Unna Boot With Calamine</i></p> <p>BOTA DE UNNA FLEXIBLE CON CALAMINA Venda Cola de Zinc • Cierre con tira de gasa</p> <p>BOTTE D'UNNA FLEXIBLE AVEC CALAMINE Bande Unna elastique • Gaze tissée</p> <p>REF 900-7455</p> <p>Bandage Size/Tamaño/Format du pansement/ Bandagengröße/Misura della fascia: 3' x 10 Yds. (7.6 cm x 9 meters)</p>	<p> HENRY SCHEIN® MEDICAL BANDAGE</p> <table border="1"><tr><td colspan="2">Drug Facts</td></tr><tr><td>Active Ingredients:</td><td>Purpose</td></tr><tr><td>Zinc Oxide 25%</td><td>Skin Protectant</td></tr><tr><td>Calamine 1%</td><td>Skin Protectant</td></tr><tr><td colspan="2">Uses:</td></tr><tr><td colspan="2">• Dries the oozing and weeping of poison ivy, poison oak, or poison sumac.</td></tr><tr><td colspan="2">• Ideal for managing extremities (e.g., varicose ulcers) requiring protection and support.</td></tr><tr><td colspan="2">Warning:</td></tr><tr><td colspan="2">For external use only.</td></tr><tr><td colspan="2">If condition worsens or does not improve within 7 days, consult a doctor.</td></tr><tr><td colspan="2">Avoid contact with eyes.</td></tr><tr><td colspan="2">Keep this and all medicines out of children's reach.</td></tr><tr><td colspan="2">Directions:</td></tr><tr><td colspan="2">• 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).</td></tr><tr><td colspan="2">• Complete bandaging to just below the knee (STEP 2).</td></tr><tr><td colspan="2">• Apply an elastic adhesive bandage (STEP 3).</td></tr><tr><td colspan="2">Other Ingredients:</td></tr><tr><td colspan="2">Acacia, Castor oil, Glycerin, and White Petrolatum.</td></tr></table>	Drug Facts		Active Ingredients:	Purpose	Zinc Oxide 25%	Skin Protectant	Calamine 1%	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.		If condition worsens or does not improve within 7 days, consult a doctor.		Avoid contact with eyes.		Keep this and all medicines out of children's reach.		Directions:		• 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 knee (STEP 2).		• Apply an elastic adhesive bandage (STEP 3).		Other Ingredients:		Acacia, Castor oil, Glycerin, and White Petrolatum.	
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HENRY SCHEIN FLEXIBLE UNNA BOOT WITH CALAMINE

zinc oxide, calamine dressing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0404-0010
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:0404-0010-03	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(0404-0010)