

## **HENRY SCHEIN FLEXIBLE UNNA BOOT - zinc oxide 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.*

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### **Drug Facts**

#### **Active Ingredients**

Zinc Oxide 25%

#### **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 0404-0009-03

HENRYSCHEIN

MEDICAL BANDAGE

A Flexible Unna Boot

BOTA DE UNNA FLEXIBLE

Venda Cola de Zinc Cierre con tira de gasa



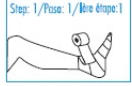
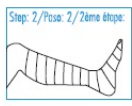
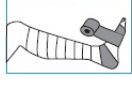


BOTTE D'UNNA FLEXIBLE

Bande Unna elastique Gaze tissee

REF 100-3444

Bandage Size/Tamaño/Format du pansement

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

 <p><b>MEDICAL BANDAGE</b></p> <p><i>A Flexible Unna Boot</i></p> <p>An impregnated gauze bandage containing zinc oxide, glycerin. Vendaje de gasa impregnada con óxido de zinc, glicerina. Bande de gaze imprégnée contenant de l'oxyde de zinc, de la glycérine.</p> <p>Store at room temperature Conserver a temperatura ambiente Conserver 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><b>MEDICAL BANDAGE</b></p> <p><b>Directions For Use/Modo de empleo/Mode d'emplo</b></p> <p><b>Step: 1/Posa: 1/1ère étape:</b>  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. Uegado 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><b>Step: 2/Posa: 2/2ème étape:</b>  Complete bandaging to just below the knee. Vende justo por debajo de la rodilla. Monter jusqu'au bas du genou.</p> <p><b>Step: 3/Posa: 3/3ème étape:</b>  Apply elastic adhesive bandage. Aplique vando elástica cohesivo. Appliquez le pansement adhésif.</p>	<p>NDC# 0404-0009-03</p>  <p><b>MEDICAL BANDAGE</b></p> <p><i>A Flexible Unna Boot</i></p> <p><b>BOTA DE UNNA FLEXIBLE</b> Venda Cola de Zinc • Cierre con tira de gasa</p> <p><b>BOTTE D'UNNA FLEXIBLE</b> Bande Unna elastique • Gaze tissée</p> <p><b>REF 100-3444</b></p> <p>Bandage Size/Tamaño/Format du pansement 3" x 10 Yds. (7.6 cm x 9 meters)</p>	 <p><b>MEDICAL BANDAGE</b></p> <p><b>Drug Facts</b></p> <table border="1"><thead><tr><th>Active Ingredients:</th><th>Purpose</th></tr></thead><tbody><tr><td>Zinc Oxide 25%</td><td>Skin Protectant</td></tr></tbody></table> <p><b>Uses:</b></p> <ul style="list-style-type: none"><li>• Dries the oozing and weeping of poison ivy, poison oak, or poison sumac.</li><li>• Ideal for managing extremities (e.g., varicose ulcers) requiring protection and support.</li></ul> <p><b>Warning:</b> 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.</p> <p><b>Directions:</b></p> <ul style="list-style-type: none"><li>• 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).</li><li>• Complete bandaging to just below the knee (STEP 2).</li><li>• Apply an elastic adhesive bandage (STEP 3).</li></ul> <p><b>Other Ingredients:</b> Acacia, Castor oil, Glycerin, and White Petrolatum.</p>	Active Ingredients:	Purpose	Zinc Oxide 25%	Skin Protectant
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# HENRY SCHEIN FLEXIBLE UNNA BOOT

zinc oxide dressing

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0404-0009
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	25 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
ACACIA (UNII: 5C5403N26O)	
CASTOR OIL (UNII: D5340Y2I9G)	
GLYCERIN (UNII: PDC6A3C0OX)	
PETROLATUM (UNII: 4T6H12BN9U)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0404-0009-03	1 in 1 BOX; Type 0: Not a Combination Product	06/06/2016	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part347	06/06/2016	

**Labeler** - Henry Schein, Inc. (012430880)

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Laboratorios Le Roy		588387394	manufacture(0404-0009)

Revised: 6/2016

Henry Schein, Inc.