

**PRIMER - zinc oxide, calamine dressing**  
**Derma Sciences Canada, 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%

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.

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

Avoid contact with eyes.

**Keep Out of Reach of Children Section**

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).
- Continue 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 (Front and Back)**

**(FRONT SIDE NDC 64772-300-05)**

NDC 64772-300-05

Primer ®

3" Modified Unna Boot with Calamine

3" Venda Bota

Unna Modificada Con Calamina

Stays moist  
to Encourage  
Healing

Permanece  
humeda para  
alentar  
la curacion

Catalog # R99903C

DERMA SCIENCES

**(FRONT SIDE NDC 64772-300-03)**

NDC 64772-300-03

Primer ®

3" Modified Unna Boot with Calamine

3" Venda Bota  
Unna Modificada Con Calamina

Stays moist  
to Encourage  
Healing

Permanece  
humeda para  
alentar  
la curacion

Catalog # GL300-1C

DERMA SCIENCES

**(BACK SIDE NDC 64772-300-03)**

Primer ®

3" Modified Unna Boot with Calamine

- Non - raveling guaze evenly impregnated with a non-hardening zinc oxide paste
- Contains no preservatives

3" Venda Unna Modificada Con Calamina

- Venda ge gasa gue no se deshila impregnada uniformemente con pasta de oxido de zinc que no se endurece.
- No contiene conservadores.

Catalog # GL300-1C

DERMA SCIENCES

GL-300-1C NDC

Catalog # **GL-300-1C**  
 4" Modified Unna Boot  
 with calamine  
 4" Venda Bota  
 Unna Modificada  
 con calamina

**Primer®**

**3" Modified Unna Boot  
 with calamine**

- Non-raveling gauze evenly impregnated with a non-hardening zinc oxide paste
- Contains no preservatives

**3" Venda Bota  
 Unna Modificada  
 con calamina**

- Venda de gasa que no se deshila impregnada uniformemente con pasta de óxido de zinc que no se endurece.
- No contiene conservadores

Catalog # **GL-300-1C**



**1** Begin bandaging with Primer® at base of toes, without pressure, keeping foot & leg at right angle. Continue bandaging beyond ankle, doubling back to ensure molding to contours of leg.

Empezar a vendar con Primer en la base de los dedos, sin ejercer presión, manteniendo el pie y la pierna en ángulo recto. Continúe vendando más allá del tobillo regresando el vendaje para asegurar seguir moldeando el contorno de la pierna.



**2** Complete bandaging to just below the knee. Termine de vendar justo abajo de la rodilla.



**3** Apply an elastic adhesive bandage. Aplique un vendaje elástico adhesivo.

Medicare Reimbursable  
 Costo Médico Reembolsable

NDC 64772-300-03

**Primer®**

**3" Modified Unna Boot  
 with calamine**

**3" Venda Bota  
 Unna Modificada  
 con calamina**

*Stays Moist  
 to Encourage  
 Healing*

*Permanece  
 húmeda para  
 alentar  
 la curación*

Catalog # **GL-300-1C**



**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.

Made in Mexico for:  
 Derma Sciences, Inc.  
 104 Shorting Road  
 Toronto, Ontario M1S 3S4  
 In USA call: 1-800-445-7627  
 In CANADA call: 1-800-387-5302

Primer® is a registered trade of Derma Sciences, Inc.  
 Primer® es un nombre comercial registrado por Derma Sciences, Inc.

40-1158-02



(FRONT SIDE NDC 64772-300-06)

NDC 64772-300-06

Primer ®

4" Modified Unna Boot with Calamine

4" Venda Bota  
Unna Modificada Con Calamina

Stays moist  
to Encourage  
Healing

Permanece  
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la curacion

Catalog # R99904C

DERMA SCIENCES

**(FRONT SIDE NDC 64772-300-04)**

NDC 64772-300-04

Primer ®

4" Modified Unna Boot with Calamine

4" Venda Bota  
Unna Modificada Con Calamina

Stays moist  
to Encourage  
Healing

Permanece  
humeda para  
alentar  
la curacion

Catalog # GL-400-1C

DERMA SCIENCES

**(BACK SIDE NDC 64772-300-04)**

Primer ®

4" Modified Unna Boot with Calamine

- Non - raveling guaze evenly impregnated with a non-hardening zinc oxide paste
- Contains no preservatives

#### 4" Venda Uma Modificada Con Calamina

- Venda ge gasa que no se deshila impregnada uniformemente con pasta de oxido de zinc que no se endurece.
- No contiene conservadores.

Catalog # GL-400-1C

DERMA SCIENCES

Catalog # **GL-400-1C**

**Primer®**  
4" Modified Unna Boot  
with calamine  
4" Venda Bota  
Unna Modificada  
con calamina

**Primer®**

**4" Modified Unna Boot  
with calamine**

- Non-raveling gauze evenly impregnated with a non-hardening zinc oxide paste
- Contains no preservatives

**4" Venda Bota  
Unna Modificada  
con calamina**

- Venda de gasa que no se deshila impregnada uniformemente con pasta de óxido de zinc que no se endurece.
- No contiene conservadores

Catalog # **GL-400-1C**



**1** Begin bandaging with Primer® at base of toes, without pressure, keeping foot & leg at right angle. Continue bandaging beyond ankle, doubling back to ensure molding to contours of leg.

Empiece a vendar con Primer en la base de los dedos, sin ejercer presión, manteniendo el pie y la pierna en ángulo recto. Continúe vendando más allá del tobillo regresando el vendaje para asegurar seguir moldeando el contorno de la pierna.



**2** Complete bandaging to just below the knee. Termine de vendar justo abajo de la rodilla.



**3** Apply an elastic adhesive bandage. Aplique un vendaje elástico adhesivo.

Medicare Reimbursable  
Costo Médico Reembolsable

NDC 64772-300-04

**Primer®**

**4" Modified Unna Boot  
with calamine**

**4" Venda Bota  
Unna Modificada  
con calamina**

*Stays Moist  
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Catalog # **GL-400-1C**



**Drug Facts**

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Zinc Oxide 25% .....	Skin Protectant
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40-1160-02



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**PRIMER**

zinc oxide, calamine dressing

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:64772-300
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC OXIDE	25 g
FERRIC OXIDE RED (UNII: 1K09F3G675) (FERRIC OXIDE RED - UNII:1K09F3G675)	FERRIC OXIDE RED	0.015 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC OXIDE	0.985 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:64772-300-03	1 in 1 BOX		
2	NDC:64772-300-05	60 in 1 BOX		
3	NDC:64772-300-04	1 in 1 BOX		
4	NDC:64772-300-06	60 in 1 BOX		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	05/10/2010	

**Labeler** - Derma Sciences Canada, Inc. (200564891)

**Registrant** - LABORATORIOS LE ROY, S.A. DE C.V. (588387394)

### Establishment

Name	Address	ID/FEI	Business Operations
LABORATORIOS LE ROY, S.A. DE C.V.		588387394	manufacture