REPARA - zinc oxide, calamine dressing PSS World Medical, 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 1.3%

Purpose

Skin Protectant

Uses

Dries the oozing and weeping of poison:

- ivy
- oak
- sumac

Warning

For external use only.

When using this product

• do not get into eyes

Stop and ask a doctor if

- Condition worsens
- symptoms last 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

- Apply as needed
- Cleanse the leg and dry the skin.
- If a wound is present, apply an appropriate wound dressing for moist wound healing.
- With a foot positioned at 90° or right angle to the leg (dorsiflexed) begin wrapping the medicated bandage without tension beginning at the base of the toes. Wrap the leg without tension overlapping each layer by 50% or half the width of the dressing. Smooth and mold the bandage while wrapping.
- Wrap all the way up the leg stopping one finger width below the posterior knee.
- Apply an elastic adhesive bandage (not included), following the manufacturer's instructions.

Other Ingredients

Acacia, Castor oil, Glycerin, and White Petrolatum.

Principal Display Panel (Front and Back)

NDC # 68345-272-01

REPARA®

3" Unna Boot w/ Calamine

- 3" x 10 yds.
- Non-hardening zinc oxide formulation
- Conforms easily to foot or leg
- Provides moist healing environment

Questions or Comments about Repara Products? 800-777-4908

Manufactured for PSS World Medical Inc. 4345 Southpoint Blvd., Jacksonville, FL 32216 Made in Mexico www.myselectonline.com

1 each/box

Reorder # 2072

Directions for Use

- 1. Cleanse the leg and dry the skin.
- 2. If a wound is present, apply an appropriate wound dressing for moist wound healing.
- 3. With the foot positioned at a 90 or right angle to the leg (dorsiflexed) begin wrapping the medicated bandage without tension beginning at the base of the toes. Wrap the leg without tension overlapping each layer by 50% or half the width of the dressing. Smooth and mold the bandage while wrapping.
- 4. Wrap all the way up the leg stopping one finger width below the posterior knee.
- 5. Apply an adhesive bandage (not included), following the manufacturer's instructions



NDC # 68345-272-02

REPARA®

4" Unna Boot w/ Calamine

• 4" x 10 yds.

- Non-hardening zinc oxide formulation
- Conforms easily to foot or leg
- Provides moist healing environment

Questions or Comments about Repara Products? 800-777-4908

Manufactured for PSS World Medical Inc. 4345 Southpoint Blvd., Jacksonville, FL 32216 Made in Mexico www.myselectonline.com

1 each/box

Reorder # 2073

Directions for Use

- 1. Cleanse the leg and dry the skin.
- 2. If a wound is present, apply an appropriate wound dressing for moist wound healing.
- 3. With the foot positioned at a 90 or right angle to the leg (dorsiflexed) begin wrapping the medicated bandage without tension beginning at the base of the toes. Wrap the leg without tension overlapping each layer by 50% or half the width of the dressing. Smooth and mold the bandage while wrapping.
- 4. Wrap all the way up the leg stopping one finger width below the posterior knee.
- 5. Apply an adhesive bandage (not included), following the manufacturer's instructions.



REPARA

zinc oxide, calamine dressing

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68345-272

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	0.0195 g		
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC OXIDE	1.2805 g		

Inactive Ingredients			
Ingredient Name	Strength		
ACACIA (UNII: 5C5403N26O)			
CASTOR OIL (UNII: D5340 Y2I9 G)			
GLYCERIN (UNII: PDC6A3C0OX)			
PETROLATUM (UNII: 4T6H12BN9U)			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:68345-272-01	1 in 1 BOX			
2	NDC:68345-272-02	1 in 1 BOX			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	05/17/2010		

Labeler - PSS World Medical, Inc. (101822682)

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

Revised: 5/2010 PSS World Medical, Inc.