LANTISEPTIC MULTI-PURPOSE- menthol, ferric oxide red and zinc oxide ointment Summit Industries, 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.

Lantis eptic Multi-Purpose Skin Ointment Drug Facts

Active Ingredients

Menthol 0.45%

Calamine 2%

Zinc Oxide 18%

Purpose

External Analgesic, Skin Protectant

Uses

A moisture barrier that prevents and helps protect skin irritations from

- urine
- diarrhea
- perspiration
- fistula drainage
- feeding tube site leakage
- wound drainage
- minor burns
- cuts
- scrapes
- itching

Warnings

- For external use only.
- When using this product
- do not get into eyes.

Stop use and ask 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

When practical, gently cleanse and dry area.

- Adults: Apply externally to affected area up to 6 times daily or after each incontinent episode or diaper change.
- Children under 12 years: Consult a doctor.

Other Information

Store at 15-30°C (59-86°F)

Inactive Ingredients:

Beeswax, Disodium EDTA, Glycerin, Lanolin, Methylparaben, Mineral Oil, Petrolatum, Propylparaben, Purified Water, Sodium Borate, Sorbitan Sesquioleate

Questions or Comments?

1-800-241-6996

SUMMIT INDUSTRIES, INC

PO Box 7329, Marietta, GA 30065

www.lantiseptic.com

Item # 0602

Image of representative container artwork

MultiPurposeSkinOintment5g.jpg









LANTISEPTIC MULTI-PURPOSE

menthol, calamine, zinc oxide ointment

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:12090-0032
Route of Administration	TOPICAL	DEA Sche dule	

Active Ingredient/Active Moiety			
Ingredient Name Basis of Strength Strengt			
MENTHOL (MENTHOL)	MENTHOL	4.5 mg in 1 g	
FERRIC OXIDE RED (FERRIC OXIDE RED)	FERRIC OXIDE RED	20 mg in 1 g	
ZINC OXIDE (ZINC OXIDE)	ZINC OXIDE	180 mg in 1 g	

Inactive Ingredients	
Ingredient Name	Strength
YELLOW WAX	
EDETATE DISO DIUM	
GLYCERIN	
LANOLIN	
METHYLPARABEN	
MINERAL OIL	
PETROLATUM	
PROPYLPARABEN	
WATER	
SODIUM BORATE	
SORBITAN SESQUIOLEATE	

I	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12090-0032-3	5 g in 1 PACKET		
2	NDC:12090-0032-4	113 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	12/30/2009	

Labeler - Summit Industries, Inc. (003279189)

Registrant - Summit Industries, Inc. (003279189)

Establishment				
Name	Address	ID/FEI	Business Operations	
Summit Industries, Inc.		003279189	manufacture(12090-0032)	

Revised: 1/2013 Summit Industries, Inc.