

OCCULUS SKIN HYDRATING TOPICAL FOAM CLO-1 ANTIFUNGAL FOAM-clotrimazole aerosol, foam
Prime Packaging, 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.

PRINCIPAL DISPLAY PANEL - 125g Can Label

Drug Facts	
Active Ingredient	Purpose
Clotrimazole 1%	Antifungal
Uses	
<ul style="list-style-type: none"> ■ For the treatment of most athlete's foot (tinea pedis) or ringworm (tinea corporis). ■ For effective relief of redness, irritation, scaling, cracking, itching, burning feet. 	
Warnings: For external use only	
Do not use on children under 2 years of age unless directed by a doctor.	
When using this product: <ul style="list-style-type: none"> ■ Avoid contact with the eyes. ■ Do not use on deep or puncture wounds, infections or lacerations. 	
Stop use and ask a doctor if <ul style="list-style-type: none"> ■ Irritation occurs or if there is no improvement within 4 weeks. 	
Contents under pressure. Protect from heat and direct sunlight. Do not puncture or incinerate. Do not store at temperatures above 120°F. If pregnant or breast feeding, ask a health professional before use.	
Keep out of reach of children to avoid accidental poisoning. In case of accidental ingestion, contact a doctor or Poison Control Center immediately. Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.	
Directions	
<ul style="list-style-type: none"> ■ Hold can upright. Shake well before each application. ■ Clean the affected area and dry thoroughly. ■ Apply a thin layer of the product over affected area twice daily (morning and night) or as directed by a doctor. ■ Supervise children in the use of this product. ■ For athlete's foot: Pay special attention to spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily. ■ For athlete's foot and ringworm, use daily for 4 weeks. ■ If condition persists longer, consult a doctor. ■ This product is not effective on the scalp or nails. 	
Inactive ingredients Water, Cetearyl ethylhexanoate, Propylene glycol, Butane, Palmitic acid, Stearic acid, Propane, PVP, Polysorbate-20, Triethanolamine, Glycerin, Dimethicone, Tocopheryl acetate, Disodium EDTA, Ubiquinone	
Questions or comments? Call toll free 1-855-317-1107	



CAUTION: CONTAINER MAY EXPLODE IF HEATED.

SKIN HYDRATING
TOPICAL FOAM

CLO-1

ANTIFUNGAL FOAM

Relief for itching
and burning feet

Helps support
skin barrier function



NET WT. 4.4 OZ (125g)



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Part # 849113 PL31096-01 Rev. 01

See bottom for lot number and exp. date.



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Manufactured for IntraDerm Pharmaceuticals
1129 N. McDowell Blvd., Petaluma, CA 94954

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clotrimazole aerosol, foam

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13630-0090
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CETEARYL ETHYLHEXANO ATE (UNII: 9M64UO4C25)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
PALMITIC ACID (UNII: 2V16EO95H1)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONES (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
UBIDECARENONE (UNII: EJ27X76M46)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	green	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0090-3	125 g in 1 CAN; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	08/01/2015	

Labeler - Prime Packaging, Inc. (805987059)

Registrant - Prime Packaging, Inc. (805987059)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Packaging, Inc.		805987059	label(13630-0090) , pack(13630-0090)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(13630-0090)

Revised: 6/2015

Prime Packaging, Inc.