FOOTLOGIX INTENSIVE CARE DIABETIC FORMULA- clotrimazole aerosol, foam KVG Group 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 Ingredient Clotrimazole 1%

Purpose

Antifungal

Use Footlogix Intensive Diabetic Formula: - with Dermal Infusion Technology for the cure and prevention of fungal infections associated with Athlete's foot fungus. This Anti-fungal, intensive care formulation provides effective relief of itching, scaling, cracking, burning, redness and irritation of the skin. Natural skin functions remain unhindered.

Warnings ■ Do not use under children 2 years of age unless directed by a doctor ■ For external use only ■ Avoid spraying into the eyes ■ Do not use on deep wounds, infections or lacerations ■ Supervise children in the use of this product

Stop use and ask a doctor if: ■ irritation occurs or if there is no improvement within 4 weeks ■ there are deep puncture wounds, infections or lacerations

Keep out of reach of children to avoid accidental poisoning. In case of accidental ingestion, contact a doctor or Poison Control Center immediately

Directions ■ Clean the affected area and dry thoroughly ■ Hold the can upright ■ Shake well before each use ■ Use sparingly twice daily for the first two weeks and continue once daily until the problem is corrected ■ When used as directed, this can contains enough mousse for approximately two months supply ■ If condition persists, consult a doctor

Caution: ■ Contents are under pressure ■ Protect from direct sunlight and do not store at temperatures above 120F/50C ■ After use, do not puncture or incinerate container ■ Spray only in a well ventilated area ■ Do not spray in presence of open flame or spark or while smoking

Inactive Ingredients Aloe Barbadensis Leaf Juice, Cetearyl Ethylhexanoate, Dimethicone, Disodium EDTA, Glycerin, Methylparaben, Phenoxyethanol, Polysorbate 20, Propylene Glycol, Propylparaben, PVP, Stearic Acid, Tocopheryl Acetate, Triethanolamine, Ubiquinone, Urea, Water.

Package Label

DERMAL INFUSION TECHNOLOGY™

intensive care mousse



- Anti-fungal treatment for healing dry, rough feet
- Non-greasy, fragrance-free



NET WT. 4.23 oz (119g)

Drug Facts

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Warnings: ■ Do not use on children under 2 years of age unless directed by a doctor ■ For external use only ■ Avoid spraying into the eyes ■ Do not use on deep wounds, infections or lacerations ■ Supervise children in the use of this product

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Made in the U.S.A.

Safety sealed for your protection. Do not use if seal is broken or missing. LOT N° & EXP DATE: See bottom



Questions: 1-888-442-4408 www.footlogixdiabetic.com. Footlogix® is a trademark of KvG Group Distributed by: KvG Group Inc. Toronto, Ontario M9C 1B2

FOOTLOGIX INTENSIVE CARE DIABETIC FORMULA

clotrimazole aerosol, foam

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	1 g in 100 g

Inactive Ingredients			
Ingredient Name	Strength		
ALOE VERA LEAF (UNII: ZY81Z83H0 X)			
CETEARYL ETHYLHEXANO ATE (UNII: 9 M6 4 UO 4 C 2 5)			
DIMETHICO NE (UNII: 92RU3N3Y1O)			

EDETATE DISO DIUM (UNII: 7FLD9 1C86K)
GLYCERIN (UNII: PDC6A3C0OX)
METHYLPARABEN (UNII: A2I8C7HI9T)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
STEARIC ACID (UNII: 4ELV7Z65AP)
ALPHA-TO COPHEROL ACETATE (UNII: 9E8X80D2L0)
TROLAMINE (UNII: 9O3K93S3TK)
UREA (UNII: 8 W8 T178 47 W)
WATER (UNII: 059QF0KO0R)

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42479-213-04	119 g in 1 CAN		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part333C	06/15/2012			

Labeler - KVG Group Inc (206932605)

Revised: 6/2012 KVG Group Inc