FOOTLOGIX - clotrimazole aerosol, spray 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

- For the cure of most athlete's foot (tinea pedis)
- ringworm (tinea corporis)

Warnings

- For external use only
- **Do not use on** children under 2 years of age unless directed by a doctor
- For external use only
- Avoid spraying into the eyes

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

Stop use and ask a doctor if

• irritation occurs or if there is no improvement within 4 weeks

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.

Directions

- Clean the affected area and dry thoroughly
- Hold can upright
- Shake can well before each use
- Spray a thin layer of the product over the 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 and ringworm, use daily for 4 weeks
- If condition persists longer, consult a doctor

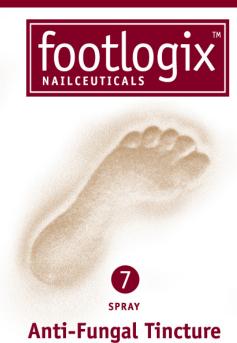
Other information

- 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.
- This product is not effective on the scalp

Unit 12, Etobicoke, Ontario, M9C 1B2 Questions: 1-888-442-4408 www.footlogix.com

Distributed by: KvG Group Inc.1 Westside Drive,

Package label



1% Clotrimazole

CAUTION:
CONTAINER MAY EXPLODE IF HEATED
FLAMMABLE

1.7 fl oz (50 ml)



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Inactive Ingredients Butane, Panthenol, Propane, Propylene Glycol (and) Persea Gratissima (Avocado) Fruit Extract, SD Alcohol 40-B, Undecylenamide DEA

LOT Nº & EXP DATE: See bottom



Product of Canada



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FOOTLOGIX

clotrimazole aerosol, spray

P	roc	luct	Inf	orma	tion

Product Type HUMAN OTC DRUG Item Code (Source) NDC:42479-212

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients	
Ingredient Name	Strength
BUTANE (UNII: 6LV4FOR43R)	

PANTHENOL (UNII: WV9CM0O67Z)		
PROPANE (UNII: T75W9911L6)		
PROPYLENE GLYCOL (UNII: 6 DC9 Q16 7 V3)		
AVO CADO (UNII: SDS87L369F)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42479-212-17	50 mL in 1 CAN		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333	09/01/2010		

Labeler - KVG Group Inc (206932605)

Establishment				
Name	Address	ID/FEI	Business Operations	
Assured Packaging Inc		248916165	manufacture	

Revised: 8/2010 KVG Group Inc