PEDESIL- clotrimazole cream
Aidance Skincare & Topical Solutions, LLC

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

Uses

- Cures finger and toe area fungal infections.
- For effective relief of itching, scaling, cracking, burning, discoloration, soreness, irritation, discomfort and chafing associated with fungal infection.

Warnings

For external use only. Do not use on children under 2 years of age unless directed by a doctor. When using this product avoid contact with eyes.

Keep out of reach of children.

If swallowed, call poison control or seek medical help.

Stop use and ask a doctor if irritation occurs or there is no improvement within 4 weeks.

Directions

- For nail care, wash and dry affected skin. Apply a thin layer of Pedesil around and under entire nail and cuticle twice daily (morning and night) or as directed by a doctor.
- If you see improvement within 4 weeks of use, you may continue use until satisfactory results are obtained.
- For athlete's foot, pay special attention to spaces between 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. Intended for use by normally healthy adults only. Persons under 18 years of age or those with highly sensitive or allergic skin should use only as directed by a doctor. Supervise children in the use of this product.

Other Information

Store at room temperature.

Inactive Ingredients

bentonite clay, distilled water, eucalyptus citriodora oil, jojoba seed oil, silver oxide, tea tree oil, zinc oxide.

Questions? 877-4-AIDANCE

PRINCIPAL DISPLAY PANEL - 28g Carton

PEDESIL

clotrimazole cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:24909-303
Route of Administration	TOPICAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	1.0 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BENTONITE (UNII: A3N5ZCN45C)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
JOJOBA OIL (UNII: 724GKU717M)	
SILVER OXIDE (UNII: 897WUN6G6T)	
TEA TREE OIL (UNII: VIF565UC2G)	
WATER (UNII: 059QF0KO0R)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24909-303-28	1 in 1 CARTON		
1		28 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	09/07/2012	

Labeler - Aidance Skincare & Topical Solutions, LLC (018950611)

Establishment

Name	Address	ID/FEI	Business Operations
Aidance Skincare & Topical Solutions, LLC		018950611	manufacture(24909-303) , label(24909-303)

Revised: 9/2012 Aidance Skincare & Topical Solutions, LLC