

TERRASIL BOIL PAIN RELIEF- benzocaine ointment

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

Benzocaine 3.5%

Purpose

Pain Reliever

Uses

For the temporary relief of pain and discomfort caused by boils.

Warnings

For external use only. Do not use for more than 3 days. **Ask a doctor before use** if you have boils on the lips, nose, cheeks, or forehead. **When using this product** avoid contact with the eyes. **Stop use and ask a doctor if** - fever occurs, - redness around the boil develops, - condition worsens or does not improve, - symptoms persist for more than 3 days, - symptoms 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

Adults and children 2 years of age and older: Apply to affected area no more than 2 times daily. Children under 2 years of age: Consult a doctor. Store at room temperature. May stain fabrics.

Inactive Ingredients

beeswax (organic), bentonite (volcanic clay), jojoba seed oil, magnesium oxide, silver oxide, tea tree oil, turmeric, zinc oxide.

PRINCIPAL DISPLAY PANEL - 44g Label

terrasil with Activated Minerals

Boil Pain Relief

Fast. Powerful. Relief.

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TERRASIL BOIL PAIN RELIEF

benzocaine ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24909-120
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	3.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BENTONITE (UNII: A3N5ZCN45C)	
JOJOBA OIL (UNII: 724GKU717M)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
SILVER OXIDE (UNII: 897WUN6G6T)	
TEA TREE OIL (UNII: VIF565UC2G)	
TURMERIC (UNII: 856YO1Z64F)	
WHITE WAX (UNII: 7G1J5DA97F)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24909-120-14	14 g in 1 JAR		
2	NDC:24909-120-44	44 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/20/2014	

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

Establishment

Name	Address	ID/FEI	Business Operations
Aidance Skincare & Topical Solutions, LLC		018950611	manufacture(24909-120) , label(24909-120)