

TERRASIL BALANITIS RELIEF- sulfur, symphytum officinale (comfrey) ointment

Aidance Skincare & Topical Solutions, LLC

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

Drug Facts

Active Ingredient

Sulfur 1X HPUS

Symphytum Officinale (Comfrey) 1X HPUS

Purpose

Sulfur - Rash Relief

Symphytum Officinale - Inflammatory Relief

Uses

Helps relieve irritated skin at the head of the penis.

Warnings

For external use only. When using this product do not use in or near eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if - symptoms persists for more than 3 days - symptoms worsen - symptoms clear up and occur again within a few days.

Directions

Adults and children 2 years of age and older: Apply to affected area 2 to 3 times per day or as needed. Children under 2 years of age: Consult a doctor.

Inactive Ingredients

allantoin, beeswax (organic), bentonite (volcanic clay), cedarwood oil, coconut oil, cotton seed oil, jojoba seed oil, lavender oil, magnesium oxide, silver oxide, stearic acid, zinc oxide.

PRINCIPAL DISPLAY PANEL - 14g Tube

All Natural

terrasil®

BALANITIS RELIEF

ALL NATURAL

terrasil®

**3X
FASTER**

BALANITIS RELIEF

NET WT 14 g

DRUG FACTS **Active Ingredients and Purpose:** Sulfur 1X HPUS - Rash Relief and Symphytum Officinale (Comfrey) 1X HPUS - Inflammatory Relief. The letters HPUS indicate the component(s) in this product is (are) officially monographed in the Homeopathic Pharmacopeia of the United States. **Uses:** Helps relieve irritated skin at the head of the penis. **Warnings:** For external use only. When using this product do not use in or near eyes. **Stop use and ask a doctor** if symptoms last more than 3 days, symptoms worsen, or 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 2 to 3 times per day or as needed. Children under 2 years of age: Consult a doctor. Store at room temperature. May stain fabrics. **Inactive Ingredients:** Allantoin, beeswax (organic), bentonite (volcanic clay)**, cedarwood oil, coconut oil, cotton seed oil, jojoba seed oil, lavender oil, magnesium oxide, silver oxide, vegetable stearic acid (naturally sourced), zinc oxide. ***3X Faster** reduction of bacteria compared to leading brands - data on file. ** May contain this ingredient.

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Homeopathic Medicine

TERRASIL BALANITIS RELIEF

sulfur, symphytum officinale (comfrey) ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24909-119
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	1 [hp_X] in 1 g
SYMPHYTUM OFFICINALE WHOLE (UNII: H8FJJ6KX5Y) (SYMPHYTUM OFFICINALE WHOLE - UNII:H8FJJ6KX5Y)	SYMPHYTUM OFFICINALE WHOLE	1 [hp_X] in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALLANTOIN (UNII: 344S277G0Z)	
BENTONITE (UNII: A3N5ZCN45C)	

CEDRUS ATLANTICA BARK OIL (UNII: ZX5QRE4U60)				
COCONUT OIL (UNII: Q9L0O73W7L)				
COTTONSEED OIL (UNII: H3E878020N)				
JOJOBA OIL (UNII: 724GKU717M)				
LAVENDER OIL (UNII: ZBP1YXW0H8)				
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)				
SILVER OXIDE (UNII: 897WUN6G6T)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
WHITE WAX (UNII: 7G1J5DA97F)				
ZINC OXIDE (UNII: SOI2LOH54Z)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24909-119-14	14 g in 1 JAR; Type 0: Not a Combination Product	06/10/2014	
2	NDC:24909-119-44	44 g in 1 JAR; Type 0: Not a Combination Product	06/10/2014	
3	NDC:24909-119-15	14 g in 1 TUBE; Type 0: Not a Combination Product	12/29/2018	
4	NDC:24909-119-50	50 g in 1 TUBE; Type 0: Not a Combination Product	12/29/2018	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic			06/10/2014	

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

Establishment

Name	Address	ID/FEI	Business Operations
Aidance Skincare & Topical Solutions, LLC		018950611	manufacture(24909-119) , label(24909-119)

Revised: 12/2018

Aidance Skincare & Topical Solutions, LLC