

12 HOUR HEALING- allantoin ointment

Skinfix, 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.

Active Ingredients

Allantoin 0.5%

Purpose

Skin protectant

Uses

HELPS HEAL DRY, CHAPPED OR CRACKED SKIN. TEMPORARILY PROTECTS MINOR CUTS, SCRAPES, AND BURNS.

Warnings

For external use only.

When using this product

- Avoid contact with eyes

WHEN USING THIS PRODUCT: AVOID CONTACT WITH EYES.

STOP USE AND ASK A DOCTOR IF

- CONDITIONS WORSENS
- SYMPTOMS LAST MORE THAN 7 DAYS OR CLEAR UP AND OCCUR AGAIN WITHIN A FEW DAYS.

KEEP OUT OF REACH OF CHILDREN.

Directions

APPLY GENEROUSLY AS NEEDED TO IRRITATED OR AFFECTED SKIN.

OTHER INFORMATION

STORE AT 65 - 80°F. MAY STAIN FABRICS. FOR ADULTS AND CHILDREN TWO YEARS OF AGE AND OLDER.

Inactive Ingredients

Aloe Barbadosensis Leaf Extract, Beeswax, Bisabolol, Butyrospermum Parkii (Shea) Butter, Cocos Nucifera (Coconut) Oil, Helianthus Annuus (Sunflower) Seed Oil, Petrolatum, Rosa Canina Fruit Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Cupuacu (Theobroma Grandiflorum) Seed Butter, Tocopherol.

Sealed Area

5mm



skinfix.
it's what we do

12-Hour Healing Ointment*
clinically proven to protect &
restore smooth, healthy skin

dermatologist recommended

natural ingredients
lanolin free

net wt 3.6 oz / 102 g

One healing product, countless uses. This natural, multi-tasking skin conditioner soothes and provides lasting protection for lips, cuticles, elbows, cracked heels and irritated skin all over the body. Cold-pressed cupuaçu butter and emollient oils of coconut and jojoba nourish and soften skin, while allantoin protects minor cuts, scrapes and burns. Help promote your skin's natural healing process with this lanolin free ointment.

Allergy tested & 0% water. NO parabens, phthalates, preservatives, lanolin, fragrance, gluten or soy.

Drug Facts	
Active Ingredients Allantoin 0.5%	Purpose Skin protectant
Uses Helps heal dry, chapped or cracked skin. Temporarily protects minor cuts, scrapes and burns.	
Warnings For external use only. When using this product Avoid contact with eyes. Stop use and ask a doctor if - condition worsens - symptoms last more than 7 days or 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 Apply generously as needed to irritated or affected skin.	
Other information Store at 65-80°F. May stain fabrics. For adults and children two years of age and older.	
Inactive Ingredients Aloe Barbadosis Leaf Extract, Beeswax, Bisabolol, Butyrospermum Parkii (Shea) Butter, Cocos Nucifera (Coconut) Oil, Helianthus Annuus (Sunflower) Seed Oil, Petrolatum, Rosa Canina Fruit Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Theobroma Grandiflorum (Cupuaçu) Seed Butter, Tocopherol.	

UPC FPO
661430 100755

Manufactured for Skinfix Inc.
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1.866.827.2793 | skinfix.com Made in Canada



Back Artwork

12 HOUR HEALING			
allanto in ointment			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:6 1328-116
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)		ALLANTOIN	0.5 g in 100 g
Inactive Ingredients			
Ingredient Name			Strength
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
YELLOW WAX (UNII: 2ZA36H0 S2V)			
LEVOMENOL (UNII: 24WE03BX2T)			
SHEANUT OIL (UNII: O88E196QRF)			
COCONUT OIL (UNII: Q9L0O73W7L)			
THEOBROMA GRANDIFLORUM SEED BUTTER (UNII: I711F13FXM)			

SUNFLOWER OIL (UNII: 3W1JG795Y)	
PETROLATUM (UNII: 4T6H12BN9U)	
ROSA CANINA FRUIT OIL (UNII: CR7307M3QZ)	
JOJOBA OIL (UNII: 724GKU717M)	
TOCOPHEROL (UNII: R0ZB2556P8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61328-116-11	102 g in 1 TUBE; Type 0: Not a Combination Product	05/02/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	05/02/2017	

Labeler - Skinfix, Inc. (203158183)

Registrant - Skinfix, Inc. (203158183)

Revised: 5/2017

Skinfix, Inc.