

## **12 HOUR MIRACLE- 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**

Restores and protects lips, cuticles and dry patches.

### **Warnings**

For external use only.

When using this product

- Avoid contact with eyes

KEEP OUT OF REACH OF CHILDREN.

### **Directions**

Apply as needed.

### **Inactive Ingredients**

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

**skinfix.**  
it's what we do

**12-Hour Miracle Ointment\***

**clinically proven to protect & restore smooth, healthy skin**

**dermatologist recommended**

**natural ingredients**

**lanolin & preservative free**

**net wt 3.6 oz / 102 g**

This natural, multi-tasking skin conditioner 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 moisturize and soften skin, while allantoin protects minor cuts, scrapes and burns. **Allergy tested & 0% water. NO parabens, silicones, fragrance, phthalates, preservatives, lanolin, gluten or soy.**

**Drug Facts**

<b>Active Ingredients</b> Allantoin 0.5%	<b>Purpose</b> Skin protectant
<b>Uses</b> Helps heal dry, chapped or cracked skin. Temporarily protects ■ minor cuts ■ scrapes ■ burns.	
<b>Warnings</b> For external use only. Do not use on ■ deep or puncture wounds ■ animal bites ■ serious burns. <b>When using this product</b> Avoid contact with eyes. <b>Stop use and ask a doctor if</b> ■ condition worsens ■ symptoms last more than 7 days or clear up and occur again within a few days. <b>Keep out of reach of children.</b> If swallowed get medical help or contact a Poison Control Center right away.	
<b>Directions</b> Apply as needed.	
<b>Other Information</b> Store at 65-80°F. May stain fabrics. For adults and children two years of age and older.	
<b>Inactive Ingredients</b> Aloe Barbadosensis Leaf Extract, Beeswax, Bisabolol, Butyrospermum Perkil (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.	
<b>Questions?</b> 1.866.927.2763	

**UPC FPO**  
**661430 100755**

Manufactured for Skinfix Inc.  
1488 Lower Water St., Suite 314  
Halifax, Nova Scotia, Canada B3J1R3  
1.866.927.2763 | skinfix.com  
Made in Canada



**12 HOUR MIRACLE**

allantoin ointment

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61328-101
<b>Route of Administration</b>	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: ZY81Z83H0X)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
LEVOMENOL (UNII: 24WE03BX2T)	
SHEANUT OIL (UNII: O88E196QRF)	
COCONUT OIL (UNII: Q9L0O73W7L)	
THEOBROMA GRANDIFLORUM SEED BUTTER (UNII: I711F13FXM)	

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61328-101-51	1 in 1 BOX	05/23/2015	
1	NDC:61328-101-11	60 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:61328-101-10	10 g in 1 TUBE; Type 0: Not a Combination Product	03/15/2017	
3	NDC:61328-101-12	102 g in 1 TUBE; Type 0: Not a Combination Product	03/15/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	05/23/2015	

**Labeler** - Skinfix, Inc. (203158183)

**Registrant** - Skinfix, Inc. (203158183)

Revised: 9/2018

Skinfix, Inc.