

**911- 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.*

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**SKINFIX - 911 OINTMENT (61328-120)**

**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 Barbadensis 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 (Jojoba) Seed Oil, Tocopherol.

consciously clean  
clinically active™

targets		
dry, cracked skin		
cuticles	heels	elbows
minor cuts, scrapes & burns		
post-procedure skin		

**free from** lanolin, water, preservatives, fragrance, steroids, antibiotics, parabens, formaldehyde, phthalates, silicones, propylene glycol, PEGs and gluten



### 911 OINTMENT

clinically proven to protect  
chapped, cracked skin  
& minor cuts & burns

skin protectant

tested & recommended  
by unbiased derms

.5% allantoin + 4% cupuaçu butter

net wt. 50 g e 1.8 oz

**.5% allantoin**  
helps promote optimal healing of minor cuts, scrapes and burns and temporarily protects chapped or cracked skin

**4% cupuaçu butter**  
helps to deeply moisturize for lasting hydration

this multi-tasking conditioner provides lasting protection for cuticles, elbows, cracked heels and irritated skin all over the body. this concentrated balm with cold-pressed cupuaçu butter, coconut oil and jojoba oil moisturizes and softens skin, while allantoin protects minor cuts, scrapes and burns. allergy tested.

#### Drug Facts

Active ingredients	Purpose
Allantoin 0.5%	Skin protectant
<b>Uses</b> Helps prevent and temporarily protects chafed, chapped or cracked skin and lips. Temporarily protects minor • cuts • scrapes • burns.	
<b>Warnings</b> For external use only. <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 generously as needed to irritated or affected skin.	
<b>Inactive Ingredients</b> Petrolatum, Helianthus Annuus (Sunflower) Seed Oil, Beeswax, Butyrospermum Parkii (Shea) Butter, Theobroma Grandiflorum (Cupuaçu) Seed Butter, Aloe Barbadosensis Leaf Extract, Rosa Canina Fruit Oil, Cocos Nucifera (Coconut) Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Tocopherol, Bisabolol.	
<b>Questions?</b> 1.866.927.2783	



## 911

allantoin ointment

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61328-120
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ALLANTOIN</b> (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	0.5 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>LEVOMENOL</b> (UNII: 24WE03BX2T)	
<b>SHEANUT OIL</b> (UNII: O88E196QRF)	
<b>COCONUT OIL</b> (UNII: Q9L0O73W7L)	
<b>THEOBROMA GRANDIFLORUM SEED BUTTER</b> (UNII: I711F13FXM)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>PETROLATUM</b> (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:61328-120-11	50 g in 1 TUBE; Type 0: Not a Combination Product	12/26/2018	
2	NDC:61328-120-12	8.5 g in 1 TUBE; Type 0: Not a Combination Product	12/26/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	12/26/2018	

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
Canadian Custom Packaging Company		207062514	manufacture(61328-120)

Revised: 12/2022

Skinfix, Inc.