

911 BALM-C- 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.

Skinfix - 911 BALM-C

Active Ingredients

Allantoin 1%

Purpose

Skin protectant

Uses

Helps prevent and temporarily protects chafed, chapped or cracked skin and lips. Temporarily protects minor

- cuts
- scrapes
- 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 to affected areas as needed.

OTHER INFORMATION

STORE AT 65-75°F. MAY STAIN FABRICS. FOR ADULTS AND CHILDREN TWO YEARS OF AGE AND OLDER.

Inactive Ingredients

Beeswax, Butyrospermum Parkii (Shea) Butter, Colloidal Oatmeal, Glycine Soja (Soybean) Oil, Paraffin, Petrolatum, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Tocopherol.

QUESTIONS?

Respond to chapped, cracked skin – fast – with a kiss of healing balm for your cheeks, around your mouth, and on sensitive, flaky eyelids. Three active, natural ingredients go to town on visible irritation and blotchiness caused by chapped and dry skin, providing targeted therapy that includes allantoin, colloidal oatmeal, and sweet almond oil. This lightweight, sheer balm is safe around eyes, and works wonders under makeup.

Non-comedogenic.
Allergy tested & 0% water.

NO fragrance, steroids, parabens, phthalates, preservatives, silicones, propylene glycol, gluten, dairy or soy.

Drug Facts

Active ingredients	Purpose
Allantoin 1%	Skin protectant

Uses: Helps prevent and temporarily protects chafed, chapped or cracked skin and lips. Temporarily protects minor
 ■ cuts ■ scrapes ■ burns.

Warnings: For external use only. When using this product Avoid direct contact with eyes. Do not use on
 ■ deep or puncture wounds ■ animal bites ■ serious burns.
 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 to affected areas as needed.

Other information: Store at 66-80°F. May stain fabrics. For adults and children two years of age and older.

Inactive Ingredients: Beeswax, Butyrospermum Parkii (Shea) Butter, Cocos Nucifera (Coconut) Oil, Colloidal Oatmeal, Paraffin, Petrolatum, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Tocopherol.

Questions? 1.866.927.2783

Manufactured for Skinfix® Inc.
1496 Lower Water St.,
Suite 314, Halifax, Nova Scotia,
Canada B3J 1R9 | 1.866.927.2783
skinfix.com | Made in Canada



clinically active,
consciously clean,

skinfix.
it's what we do

911 Balm – C

1% allantoin
3% colloidal oatmeal
7% sweet almond oil

net wt. 0.48 oz / 13.5 g



1% allantoin
Helps heal minor cuts, scrapes & burns.




3% colloidal oatmeal
Helps soothe visible blotchiness caused by chapped and cracked skin.



7% sweet almond oil
Helps nourish dry skin and relieve itching.

100% clean.
ophthalmologist
tested &
dermatologist
recommended.



911 Balm - C

1% allantoin
3% colloidal oatmeal
7% sweet almond oil

net wt. 0.48 oz / 13.5 g

Designed to soothe visible irritation and redness caused by chapped, cracked and dry skin on the cheeks, around the mouth and even on sensitive, flaky eyelids. Ophthalmologist tested and Dermatologist recommended. NO fragrance, parabens, preservatives, silicone, propylene glycol, gluten, dairy or soy.

Drug Facts	
Active Ingredients	Purpose
Allantoin 1%	Skin protectant
Use: Helps prevent and temporarily protects chapped, chapped or cracked skin and lips. Temporarily protects minor cuts, scrapes, burns.	
Warnings: For external use only. When using this product Avoid direct contact with eyes. Do not use on deep or puncture wounds, animal bites, serious burns. Stop use and ask a doctor if condition worsens or 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 to affected areas as needed.	
Other Information: Store at 65-80°F. May stain fabrics. For adults and children two years of age and older.	
Inactive Ingredients: Beeswax, Butyrospermum Parviflora (Shea) Butter, Colloidal Oatmeal, Glycine Soja (Soybean) Oil, Paraffin, Polystyrene, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Tocopherol.	
Questions? 1.888.627.2765	
Manufactured for Skinfix® Inc. 1496 Lower Water St., Suite 314, Halifax, Nova Scotia, Canada B3J1P8 1.888.627.2765 skinfix.com Made in Canada	

911 BALM-C

allantoin ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:6 1328-118
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)		ALLANTOIN	1 g in 100 g	
Inactive Ingredients				
		Ingredient Name	Strength	
		OATMEAL (UNII: 8PI54V663Y)		
		YELLOW WAX (UNII: 2ZA36H0S2V)		
		SHEA BUTTER (UNII: K49155WL9Y)		
		COCONUT OIL (UNII: Q9L0O73W7L)		
		PARAFFIN (UNII: I9O0E3H2ZE)		
		PETROLATUM (UNII: 4T6H12BN9U)		
		ALMOND OIL (UNII: 66YXD4DKO9)		
		JOJOBA OIL (UNII: 724GKU717M)		
		TOCOPHEROL (UNII: R0ZB2556P8)		
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61328-118-51	1 in 1 BOX	08/11/2018	
1	NDC:61328-118-11	13.5 g in 1 TUBE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	02/27/2017		

Labeler - Skinfix, Inc. (203158183)

Registrant - Skinfix, Inc. (203158183)