

LABISAN- cold sore care ointment
Labisan Americas, LLC.

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.

Zinc Oxide 20% part347 (suncreeen) and 1.4% Phenol (Astringent) (part 310.545(a)(18)(ii).10b, #7- Phenol 0.5 - 1.5% within Monograph, Title 21 active ingredients..

Active ingredients

Active Ingredients Purpose

Zinc Oxide 20.00%.....Cold sore/fever blister treatment/first aid/ sun protectant

Phenol 4.00%.....Cold sore/fever blister treatment/first aid antiseptic

Sulfur Praecipitotum 10.00%.....Cold sore/fever blister treatment/first aid antiseptic

Inactive Ingredients

inactive ingredients Talcum, vaseline, shea butter, paraffin, Olive oil, castor oil, iron oxide yellow and red (for color).

Keep out of reach Children

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away at 1-800-222-1222.

Stop using and consult a doctor if the condition persists or gets worse. Do not use longer than 2 weeks unless directed by a doctor.

Warnings

For external use only: Do not use in the eyes, or apply over large areas of the body.

In case of deep or puncture wounds, animal bites, or serious burns, consult a physician.

Directions

• Directions

clean the affected area at first sign of tingling, burning sensation, or itching.

apply a small amount of this products to the lips and nose prior to exposure to the sun.

in case of cold sore/fever blister indication, apply to area of sensation.

apply up to 4 times a day, and in the evening.

rub in gently.

wash hands before and after applying cream.

do not share product with anyone.
children under 12 years of age: consult a Physician

Uses

Uses

for treatment of cold sores/fever blisters on the lips, face, and/or nose

temporarily relieves the symptoms of itching and pain associated with cold sores/fever blisters

prevents outbreak of cold sore/fever blister if applied at first indication of an outbreak (tingle, or burning sensation)

heals cold sore/fever blisters

prevents and heals sun burn to lips and stimulates rapid healing

Precautions Allergy alert. When using product, Stop and consult Physician,

Warnings

For external use only: Do not use in the eyes, or apply over large areas of the body.

In case of deep or puncture wounds, animal bites, or serious burns, consult a physician.

Allergy alert: Do not use this product if you are allergic or hypersensitive to any of the ingredients in this product.

When using this product: Do not get in eyes. Use only as directed.

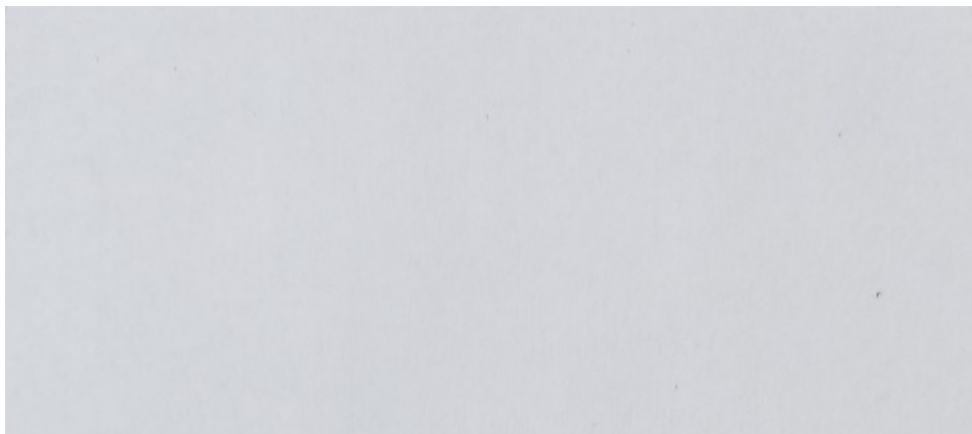
Stop using and consult a doctor if the condition persists or gets worse. Do not use longer than 2 weeks unless directed by a doctor.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away at 1-800-222-1222.

Do not get in eyes. Use only as directed.

Use Dosage..Topical

Principal display panel



Drug Facts

Active Ingredients

Zinc Oxide 20.00%.....Cold sore/fever blister treatment/first aid/ sun protectant
Phenol 1.40%.....Cold sore/fever blister treatment/first aid antiseptic

Purpose

Uses

For treatment of cold sores/fever blisters on the lips or nose.

- Temporarily relieves the symptoms of itching and pain associated with cold sores/fever blisters.
- Prevents outbreak of cold sore/fever blister if applied at first indication of an outbreak (tingle, or burning sensation).

Warnings

For external use only: Do not use in the eyes or apply over large areas of the body.

In case of deep or puncture wounds, animal bites, or serious burns, consult a physician.

Allergy alert: Do not use this product if you are allergic or hypersensitive to any of the ingredients in this product.

When using this product: Do not get in eyes. Use only as directed.

Stop using and consult a physician if the condition persists or gets worse. Do not use longer than 2 weeks unless directed by a physician.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away at 1-800-222-1222.

Directions

- Clean the affected area at first sign of tingling, burning sensation, or itching.
- Apply a small amount of this product to the lips or nose prior to exposure to the sun.
- In case of cold sore/fever blister indication, apply to area of sensation.
- Apply up to 4 times a day, and in the evening.
- Rub in gently.
- Wash hands before and after applying cream.
- Do not share product with anyone.
- Keep out of reach of children.
- Children under 12 years of age: Consult a physician.

Other information Store at room temperature.

Inactive ingredients castor oil, ferric oxide red, ferric oxide yellow, Olive oil, paraffin, Talcum, vaseline.

Questions or comments?

E-Mail us at LabisanAmericas@gmail.com

Serious side effects associated with use of this product may be reported to this E-Mail Address.

If you are not completely satisfied with Our Product, please mail a copy of receipt and any remaining product to address below and call us at 1800- Labisan (522-4726).

Distributed for Lupuca Pharma GmbH by Labisan Americas, LLC, Norwalk, CT 06851. Made in Austria.
LOT221417 A Item # 71625 EXP 11/2019

LABISAN

cold sore care ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72892-932
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
PHENOL (UNII: 339NCG44TV) (PHENOL - UNII:339NCG44TV)		PHENOL	1.4 mg in 100 mg	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	20 mg in 100 mg	
Inactive Ingredients				
Ingredient Name			Strength	
OLIVE OIL (UNII: 6UYK2W1W1E)				
SHEA BUTTER (UNII: K49155WL9Y)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
CASTOR OIL (UNII: D5340Y2I9G)				
PARAFFIN (UNII: I9O0E3H2ZE)				
FERRIC OXIDE YELLOW W (UNII: EX438O2MRT)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72892-932-72	6.7 mg in 1 TUBE; Type 0: Not a Combination Product	02/28/2019	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part347		02/22/2019	

Labeler - Labisan Americas, LLC. (105632604)

Registrant - Labisan Americas, LLC. (105632604)

Establishment			
Name	Address	ID/FEI	Business Operations
Lupuca Pharma GmbH		301826819	manufacture(72892-932)