

LABISAN COLD SORE- cold sore care ointment
Lupuca Pharma GmbH

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.

Labisan cold sore/fever blister treatment

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

Zinc Oxide 20.00%.....

Phenol 1.40%.....

Inactive Ingredients

Inactive ingredients: castor oil, ferric oxide red, ferric oxide yellow, olive oil, paraffin, talcum, vaseline.

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.

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Warnings

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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.

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Directions

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.

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
Full UVA and UVB (Broad Spectrum) Sunburn Prevention.

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 Physician 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.

Indications and Usage

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).

Other information: Store at room temperature.

Do not get in eyes. Use only as directed.

Spanish Version of insert.

Drug Facts

Ingredientes activos y propósito:

Óxido de cinc 20.00% Tratamiento de ampollas febril / úlceras bucales / primeros auxilios / protector solar

Phenol 1.40% Tratamiento de ampolla febril / antiséptico de primeros auxilios

Usos

- Para el tratamiento del herpes labial / ampollas en los labios o la nariz.
 - Alivia temporalmente los síntomas de picazón y dolor asociado con el herpes labial / ampollas febriles.
 - Previene el brote de herpes labial / ampolla febril si se aplica al primer indicio de un brote (cosquilleo o sensación de ardor).
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Advertencias

Solo para uso externo: no usar en los ojos ni aplicar sobre grandes áreas del cuerpo.

En caso de heridas profundas o punzantes, mordeduras de animales o quemaduras graves, consulte a un médico.

Alerta de alergia: No use este producto si es alérgico o hipersensible a cualquiera de los ingredientes de este producto.

Al usar este producto: No entrar en los ojos. Utilizar sólo según las indicaciones.

Deje de usar y consulte a un médico si la condición persiste o empeora. No lo use por más de 2 semanas a menos que lo indique un médico.

Mantener fuera del alcance de los niños. En caso de ingestión, obtenga ayuda médica o comuníquese con un Centro de control de intoxicaciones de inmediato al 1-800-222-1222.

Direcciones

- Limpie el área afectada a la primera señal de hormigueo, sensación de ardor o picazón.
 - Aplique una pequeña cantidad de este producto en los labios o la nariz antes de exponerse al sol.
 - En caso de dolor, herpes labial, fiebre, aplique en el área de la sensación.
 - Aplicar hasta 4 veces al día, y por la noche.
 - Frote suavemente.
 - Lavarse las manos antes y después de aplicar la crema.
 - No compartir el producto con nadie.
 - Mantener fuera del alcance de los niños.
 - Niños menores de 12 años: consultar a un médico.
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Otra información: Almacenar a temperatura ambiente.

Ingredientes inactivos: talco, vaselina, , parafina, oleum olivae, oleum ricini, óxido de hierro amarillo y rojo (color).

¿Preguntas o comentarios?

Envíenos un correo electrónico a LabisanAmericas@gmail.com

Los efectos secundarios graves asociados con el uso de este producto pueden informarse a esta dirección de correo electrónico.

Si no está completamente satisfecho con nuestro producto, envíe por correo una copia del recibo y el producto restante a la dirección que figura a continuación y llámenos al 1800 Labisan (522-4726).

Distribuido para Lupuca Pharma GmbH por Labisan Americas, LLC. Norwalk, CT 06851. Hecho en

Austria.

LOT221417 A Artículo # 71625 CAD 11/2019

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Distribuido para Lupuca Pharma GmbH., Por su Distribuidor Autorizado Exclusivo, Labisan Americas, LLC. (EE. UU., Canadá, Centro y Sudamérica), Norwalk, Connecticut 06851, Hecho en Austria desde 1931.

Si tiene interés en llevar alguno de nuestros productos Labisan Lip Care, contáctenos en LabisanAmericas@gmail.com, Attn.: New Sales.

Use Topical

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).



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).

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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

cold sore care ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72941-932
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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PHENOL (UNII: 339NCG44TV) (PHENOL - UNII:339NCG44TV)		PHENOL	1.4 g in 100 g	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	20 g in 100 g	
Inactive Ingredients				
Ingredient Name			Strength	
OLIVE OIL (UNII: 6UYK2W1W1E)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
CASTOR OIL (UNII: D5340Y2I9G)				
TALC (UNII: 7SEV7J4R1U)				
PETROLATUM (UNII: 4T6H12BN9U)				
MINERAL OIL (UNII: T5L8T28FGP)				
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)				
Product Characteristics				
Color	red (dusky pink)	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72941-932-72	6.7 g in 1 TUBE; Type 0: Not a Combination Product	03/07/2019	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part347		03/07/2019	

Labeler - Lupuca Pharma GmbH (301826819)

Registrant - Lupuca Pharma GmbH (301826819)

Establishment

Name	Address	ID/FEI	Business Operations
Lupuca Pharma GmbH		301826819	manufacture(72941-932) , pack(72941-932) , label(72941-932)

Revised: 11/2019

Lupuca Pharma GmbH