

CAREONE COLD SORE TREATMENT- camphor, menthol, phenol, white petrolatum gel
American Sales Company

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.

American Sales Company Cold Sore Treatment Drug Facts

Active ingredients

Camphor 3.00%

Menthol 1.00%

Phenol 1.50%

White Petrolatum 89.20%

Purpose

Cold sore/fever blister treatment

Skin Protectant

Uses

- For treatment of cold sores/fever blisters on the face or lips
- Temporarily relieves the symptoms of itching and pain associated with cold sores/fever blisters
- Temporarily protects minor cuts, scrapes, burns, and sores
- Helps prevent and temporarily protects chapped or cracked skin and lips

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 if you are allergic to any of the ingredients in this product.

When using this product

avoid contact with eyes. Use only as directed.

Stop use and consult a doctor if

the condition persists or gets worse. Do not use longer than 1 week 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.

Directions

- Clean the affected area
- Apply a small amount of this product to the affected area 1 to 3 times daily
- Rub in gently

- May be covered with a sterile bandage
- Wash hands before and after applying cream
- Do not share this product with anyone
- **Children under 12 years of age:** ask a doctor

Other information

store at room temperature

Inactive ingredients

Eucalyptol, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Thymol, Tocopheryl Nicotinate

Questions or comments?

Call us toll-free at 1-877-242-3234 Monday-Friday, 9 a.m. to 5 p.m. EST.

Serious side effects associated with use of this product may be reported to this number.

Package/Label Principal Display Panel

MAXIMUM STRENGTH

Camphor 3.00%, Menthol 1.00%, Phenol 1.50%, White Petrolatum 89.20%

COLD SORE TREATMENT

Cold Sore/Fever Blister Treatment & Skin Protectant

New & Improved

TEMPORARY RELIEF OF PAIN & DISCOMFORT

Paraben Free

With Tea Tree Oil

Medicated

Phthalate Free

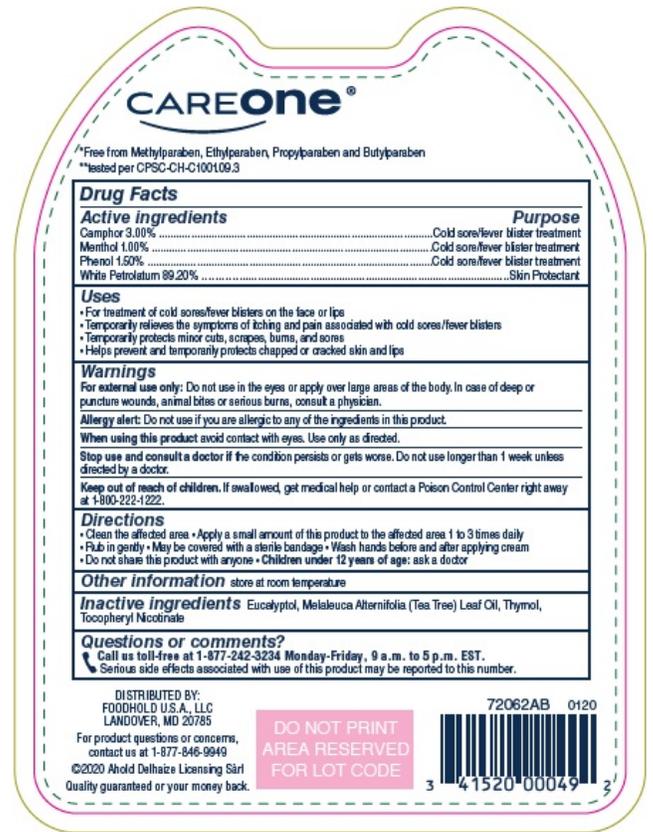
Sulfate Free

Works on Contact

Applies Clear

OUR PHARMACISTS RECOMMEND

NET WT 0.07 oz (2.0 g)



CAREONE COLD SORE TREATMENT

camphor, menthol, phenol, white petrolatum gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-097
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	30 mg in 1 g
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	10 mg in 1 g
PHENOL (UNII: 339NCG44TV) (PHENOL - UNII:339NCG44TV)	PHENOL	15 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	892 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
EUCALYPTOL (UNII: RV6J6604TK)	
MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K)	
THYMOL (UNII: 3J50XA376E)	

TOCOPHERYL NICOTINATE, D- α . (UNII: W1J5UCY5C)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-097-01	1 in 1 PACKAGE	03/11/2020	
1		2 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 not final	part333E	03/11/2020	

Labeler - American Sales Company (809183973)

Revised: 3/2020

American Sales Company