

CANKER COMPLETE CANKER SORE RELIEF- menthol cream
Wasatch Product Development

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.

Canker Complete

Active ingredient	Purpose
Menthol 0.5%	Oral Pain Reliever

Uses For the temporary relief of pain associated with canker and mouth sores

Keep this and all drugs out of reach of children

Stop use and ask a dentist or physician if

- Sore mouth symptoms do not improve in 7 days
- Irritation, pain or redness worsens
- Swelling, rash or fever develops

Do not use this product for more than 7 days unless directed by a health professional

Directions

Adults and children 2 years and older cotton swab or fingertip	Gently dab medication on the site of irritation with a
a dentist or physician	Apply to the affected area up to 4 times a day, or as directed by

Children under 12 years	Adult supervision should be given in the use of this product
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Children under 2 years	Consult dentist or physician
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Inactive ingredients:

Calcium/Sodium PVM/MA Copolymer, TX-Factor 5 tm (proprietary polypeptide lipid blend), Cellulose Gum, Mineral Oil, Petrolatum, Lecithin, Chlorella Vulgaris Extract, Hydrolyzed Lupine Protein, Silica, C12-15 Alkyl Benzoate, Tribehenin, Ceramide 2, PEG-10 Rapeseed Sterol, Tetrasodium EDTA, Flavor, Melaleuca Alternafolia (Tea Tree) Leaf Oil, Caprylyl Glycol, Stearyl Glycyrhretinate, Sucralose, DC Red Lake 27

canker
complete™

effectively treats the 5 factors
of canker and mouth sores

Drug Facts

Active Ingredients Menthol 0.5% **Purpose** Oral Pain Reliever

Inactive Ingredients Calcium/Sodium PVM/MA Copolymer, TX-Factor 5 tm (proprietary polypeptide lipid blend), Cellulose Gum, Mineral Oil, Petrolatum, Lecithin, Chlorella Vulgaris Extract, Hydrolyzed Lupine Protein, Silica, C12-15 Alkyl Benzene, Tribehenin, Ceramide 2, PEG-10 Rapeseed Sterol, Tetrasodium EDTA, Flavor, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Caprylyl Glycol, Stearyl Glycyrhizinate, Sucralose, D&C Red Lake #27

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Directions

Adults and children 2 years and older	Gently dab medication on the site of irritation with a cotton swab or fingertip. Apply to the affected area up to 4 times a day, or as directed by a dentist or physician.
Children under 12 years	Adult supervision should be given in the use of this product.
Children under 2 years	Consult dentist or physician.

Warnings Do not use this product for more than 7 days unless directed by a health professional.

Stop use and ask a dentist or physician if: • sore in mouth symptoms do not improve in 7 days • irritation, pain or redness worsens • swelling, rash or fever develops

• Do not exceed recommended dosage • Avoid contact with eyes

Keep this and all drugs out of reach of children

Manufactured for:
Canker Complete
Draper, UT 84020 USA
Questions or Comments? Please visit
www.cankercomplete.com
US PATENT PENDING. MADE IN USA



TX5
FACTOR

THE MOST POWERFUL
CANKER AND MOUTH SORE
TREATMENT FEATURING

The complete canker and mouth sore solution
cankercomplete.com

The only solution that targets
all 5 factors of canker and mouth sores
Rapid Pain Relief • Promotes Healing • Powerful Protective Barrier
Reduces Inflammation • Protects Against Infection

Net wt. 0.21 oz (6g)

canker
complete™

Periodontist Recommended

Canker Complete Net wt. .21oz (6g)



For the temporary relief of pain associated with canker and mouth sores.

Directions:

Gently dab medication on the site of irritation with a cotton swab or fingertip. Apply to the affected area up to 4 times a day, or as directed by a dentist or physician.

Warnings:

Do not use this product for more than 7 days unless directed by a health professional. Do not exceed recommended dosage. Avoid contact with eyes. Keep this and all drugs out of reach of children.

Active Ingredient: Menthol 0.5%

Canker Complete, Draper, UT 84020, www.cankercomplete.com

CANKER COMPLETE CANKER SORE RELIEF			
menthol cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44717-890
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			

Ingredient Name		Basis of Strength	Strength	
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)		Menthol	0.5 g in 100 g	
Inactive Ingredients				
Ingredient Name		Strength		
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)				
MINERAL OIL (UNII: T5L8T28FGP)				
PETROLATUM (UNII: 4T6H12BN9U)				
CHLORELLA VULGARIS (UNII: RYQ4R60M02)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)				
TRIBEHENIN (UNII: 8OC9U7TQZ0)				
CERAMIDE 2 (UNII: C04977SRJ5)				
PEG-10 RAPESEED STEROL (UNII: 258O76T85M)				
EDETATE SODIUM (UNII: MP1J8420LU)				
TEA TREE OIL (UNII: VIF565UC2G)				
CAPRYLYL GLYCOL (UNII: 00YIU5438U)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44717-890-02	1 in 1 BOX	10/12/2010	
1	NDC:44717-890-01	6 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	part341	10/12/2010		

Labeler - Wasatch Product Development (962452533)

Registrant - Wasatch Product Development (962452533)

Establishment

Name	Address	ID/FEI	Business Operations
Wasatch Product Development		962452533	manufacture(44717-890)