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

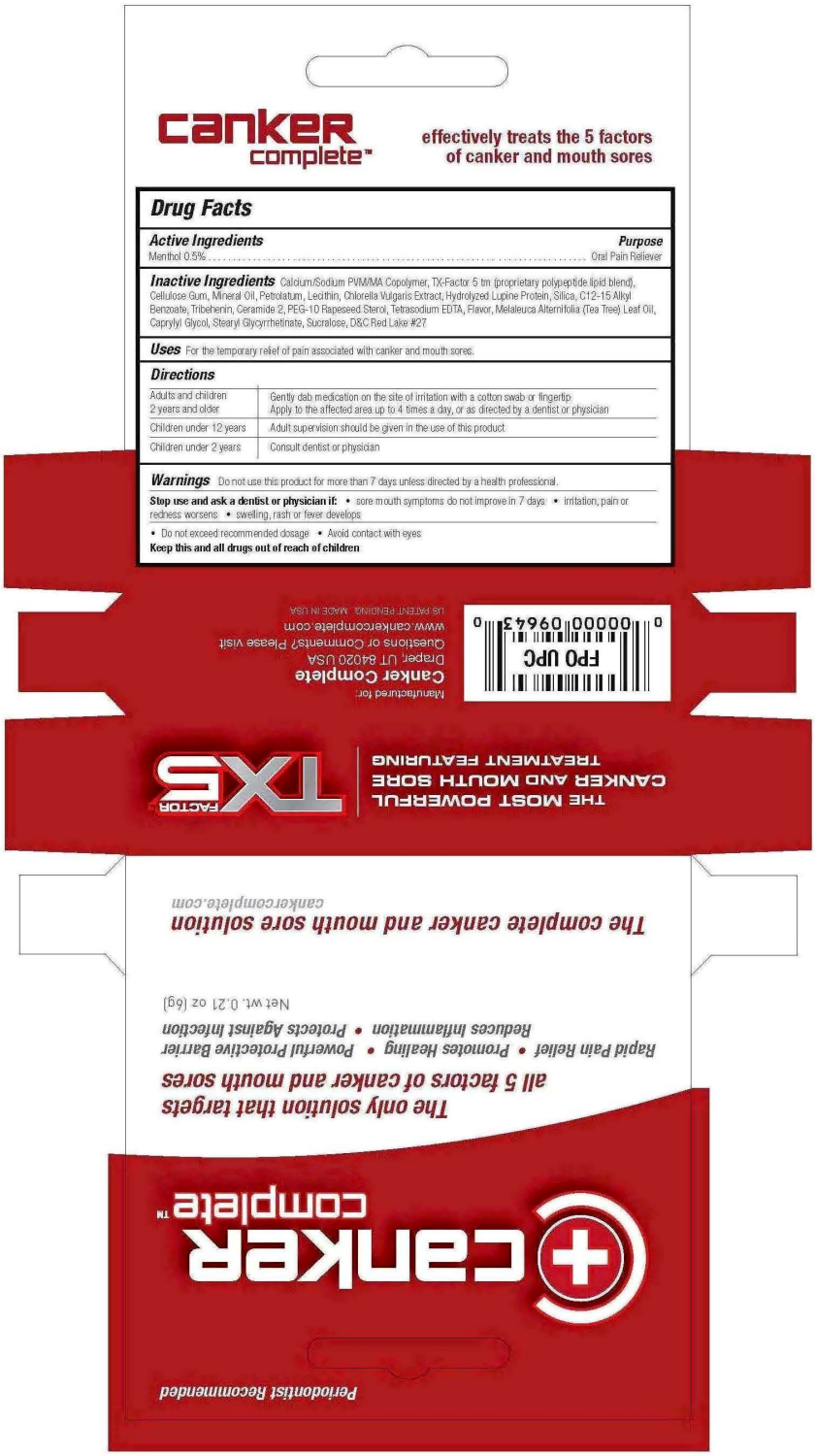
Do not use this product for more than 7 days unless directed by a health professional

Directions

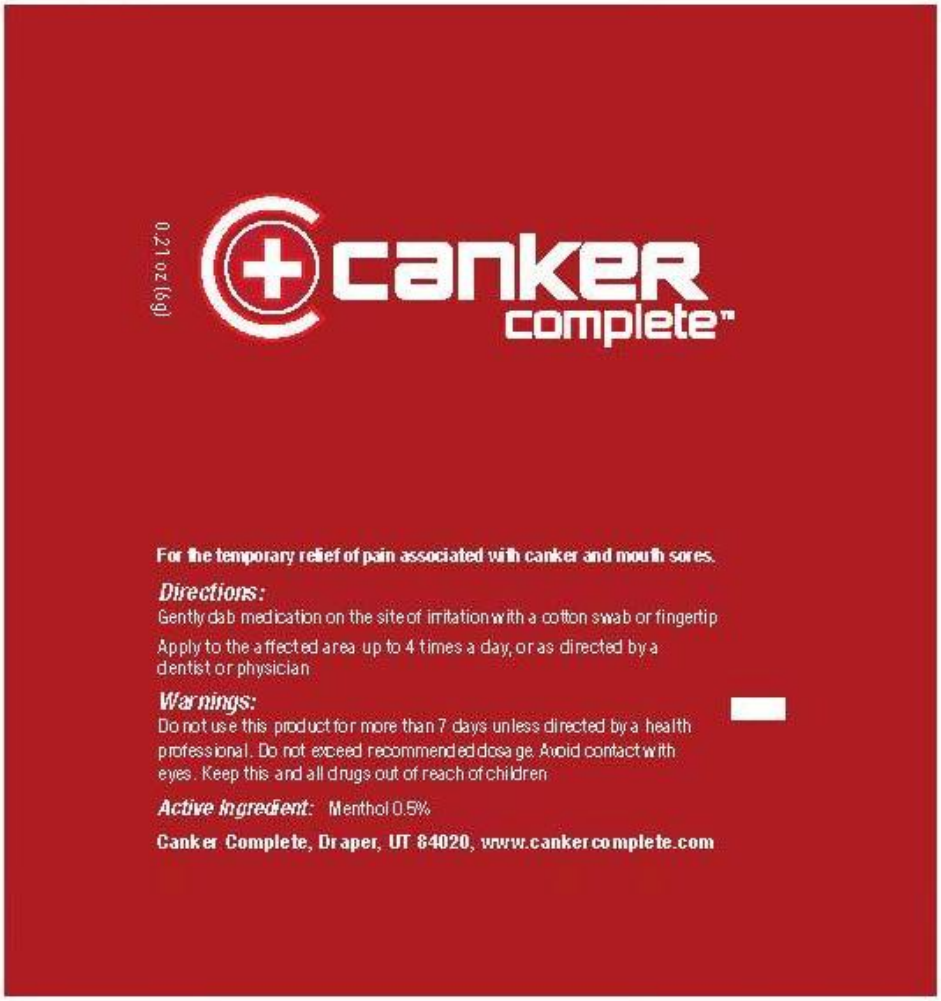
Adults and children 2 years and older	Gently dab medication on the site of irritation with a cotton swab or fingertip Apply to the affected area up to 4 times a day, or as directed by a dentist or physician
Children under 12 years	Adult supervision should be given in the use of this product
Children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

Inactive ingredients:

Calcium/Sodium PVM/MA Copolymer, TX-Factor 5 tm (propietary 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 Glycyrrhetinate, Sucralose, DC Red Lake 27



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



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)

Revised: 5/2017 Wasatch Product Development