DENTEMP CANKER SORE SINGLE DOSE- dentemp canker sore tablet, extended release Team Technologies, Inc

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.

DenTemp Canker Cover- canker cover tablet, extended relief

Active Ingredient (per each tablet)

Menthol 2.5 mg

Indications and Usage

For the temporary relief of pain associated with canker sores

Warnings

Do not use this product for more than 7 days unless directed by a dentist or doctor.

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

Do not exceed recommended dosage.

WARNINGS

Keep out of reach of children. In case of accidental overdose, get medical help or contact a

Poison Control Center (1-800-222-1222) right away.

PREGNANCY OR BREASTFEEDING

If pregnant, or breast-feeding or taking prescription drugs, ask a health care professional - before use

Directions .adults and children 5 years of age and older, apply up to 3 tablets per day,

as needed. Place the tablet on a clean, dry finger with the white side up. Place the white side on

the sore and hold in place for 10 seconds. If sore is difficult to reach (in the fold between the

cheek and gum or near the teeth or lip) break the tablet along the score and use half. Some

discomfort may occur during the first few minutes, but will quickly subside, followed by hours of

soothing relief. Within 30 minutes the tablet forms a clear, gel-like bandage that seals and

protects the sore for hours before dissolving. Do not remove the tablet before it dissolves. In

case of discomfort, the tablet may be removed by gently peeling the tablet from the sides while

washing with warm water. Do not use any instrument to remove the tablet.

.children under 5 years, ask a doctor

Other information store in a cool, dry place.

Inactive ingredients annato, carbomer homopolymer type a, citrus oil, hydroxypropyl - cellulose, magnesium chloride, povidone K30, povidone K90, silicon dioxide, xylitol

Questions or comments? 833-363-2763 or consumeraffairs@doc-brands.com

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Purpose

Oral Pain Reliever

Dentemp Canker Sore Cover Principal Display Panel



https://lh3.googleusercontent.com/b IYh2tsbaVrFKjivTRF3TBShQE0y7kGgx4X58-7zz-

bvDSokUD0GXphYuB1uiByZerzbw=s85

DenTemp

Canker Cover

Oral Pain Reliever

Clinically Proven

To Relieve Pain & Heat Sores

Helps Heal as Fast as 1 Day

Soothing Relief Up to 12 Hours

Stays on While Eating

6 count

Canker Sore

DENTEMP CANKER SORE SINGLE DOSE

dentemp canker sore tablet, extended release

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:67659-160(NDC:73653-211)

Route of Administration ORAL, TOPICAL

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)
MENTHOL
2.5 mg in 150 mg

Inactive Ingredients Ingredient Name POVIDONE K90 (UNII: RDH86HJV5Z) ANNATTO (UNII: 6PQP1V1B6O) CARBOMER HOMOPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: F68VH75CJC) MAGNESIUM CHLORIDE (UNII: 02F3473H9O) CITRUS LIMON FRUIT OIL (UNII: 0HNC1|1YED)

HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)

SILICON DIOXIDE (UNII: ETJ7Z6XBU4) **POVIDONE K30** (UNII: U725QWY32X)

XYLITOL (UNII: VCQ006KQ1E)

Product Characteristics

Color	pink (Pink (one side pink, one side white))	Score	no score
Shape	ROUND	Size	10mm
Flavor	CITRUS	Imprint Code	

Contains

l	Packaging						
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
	1	NDC:67659-160- 07	6 mg in 1 CARTON; Type 0: Not a Combination Product	04/05/2021			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part356	04/05/2021			

Labeler - Team Technologies, Inc (192339703)

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