

**DENTEK CANKER COVER- menthol patch, extended release**  
**DenTek Oral Care, Inc.**

-----  
**DenTek Canker Cover 60630-091**

***Active ingredient(per each patch)***

Menthol 2.5 mg

***Purpose***

Oral pain reliever

***Uses***

for the temporary relief of pain associated with:

- canker sores
- mouth sores
- minor irritation of the mouth and gums.

***Warnings***

**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

**If pregnant or breast-feeding or taking prescription drugs,**

ask a health care professional before use.

**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.

***Directions***

- **adults and children 5 years of age and older,** apply up to 3 times a day, as needed

The sore should be dry (pat with tissue) if possible. Place the patch on a clean, dry finger with the white side up. Place the white side on the sore and hold in place for 20 seconds. If sore is difficult to reach (in the fold between the cheek and gum or near the teeth or lip) break the patch 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 patch before it

dissolves. In case of discomfort, the patch may be removed by gently peeling the tablet from the sides while washing with warm water. Do not use any instrument to remove the patch.

- **children under 5 years, ask a doctor**

### ***Other information***

store in a cool dry place.

### ***Inactive ingredients***

annatto, carbomer homopolymer type a, flavor, hydroxypropyl cellulose, potassium magnesium chloride hydrate, povidone K30, povidone K90, silicon dioxide, xylitol

### ***Questions***

800-4DENTEK (433-6835)

### **PRINCIPAL DISPLAY PANEL**

DenTek  
CANKER COVER  
CANKER SORE PATCH  
6 COUNT



## DENTEK CANKER COVER

menthol patch, extended release

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60630-091	
Route of Administration	TRANSMUCOSAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	2.5 mg in 194.85 mg	
Inactive Ingredients				
Ingredient Name			Strength	
ANNATTO (UNII: 6PQP1V1B6O)				
CARBOMER HOMOPOLYMER TYPE A (UNII: F68VH75CJC)				
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)				
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)				
POVIDONE K30 (UNII: U725QWY32X)				
POVIDONE K90 (UNII: RDH86HJV5Z)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
XYLITOL (UNII: VCQ006KQ1E)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60630-091-02	6 in 1 CARTON	11/11/2015	
1	NDC:60630-091-01	2.5 mg in 1 DOSE PACK; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M022	11/11/2015	

**Labeler -**
DenTek Oral Care, Inc. (153818646)