

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

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**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



**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:60630-091
<b>Route of Administration</b>	TRANSMUCOSAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.5 mg in 194.85 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
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**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC MONOGRAPH NOT FINAL	part356	11/11/2015	

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

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DenTek Oral Care, Inc.