

DENTEK CANKER COVER- menthol patch, extended release
Bershtel Enterprises

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.

Active Ingredient

menthol: 2.5 mg

Keep Out of Reach of Children Section

Warning: Keep out of reach of children.

Purpose Section

For Relief of pain associated with: canker sores & mouth sores.

Ask Doctor

Consult your dentist or doctor before using.

Indications & Usage

Adult and Children 5 year of age and older.

The sore should be dry (pat with tissue) is possible. Place the Canker Cover 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. Within 30 minutes the tablet forms a clear, gel-like bandage that seals and protects the sore for hours before dissolving. **DO NOT REMOVE PATCH BEFORE IT DISSOLVES.**

Dosage & Administration

2.5 mg per patch

Questions section

Call us 800-4Dentek (433-6835) M-F 8am - 5am EST or email us at Info@Dentek.com

Warning Section

Keep out of reach of children. If irritation, pain, or redness worsens, if swelling, rash or fever develops, or if sore mouth systems persists for 7 days, see your doctor or dentist.

Inactive Ingredients

1. citrus medica fruit
2. povidone
3. colloidal silicon dioxide
4. carbomer 934
5. Xylitol
6. Hydroxypropyl

7. sea salt
8. magnesium stearate
- 9.



DENTEK CANKER COVER

menthol patch, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10564-0910
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

Inactive Ingredients

Ingredient Name	Strength
CITRUS MEDICA FRUIT (UNII: ZE5Q6PN9ON)	
CARBOMER 934 (UNII: Z135WT9208)	
POVIDONE (UNII: FZ989GH94E)	
HYDROXYPROPYL CELLULOSE (TYPE E) (UNII: 66O7AQV0RT)	

SEA SALT (UNII: 87GE52P74G)	
XYLITOL (UNII: VCQ006KQ1E)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color		Score	
Shape	ROUND	Size	9mm
Flavor	MENTHOL	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10564-0910-2	1 in 1 CARTON; Type 0: Not a Combination Product	12/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	12/01/2015	

Labeler - Bershtel Enterprises (066659129)

Revised: 12/2015

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