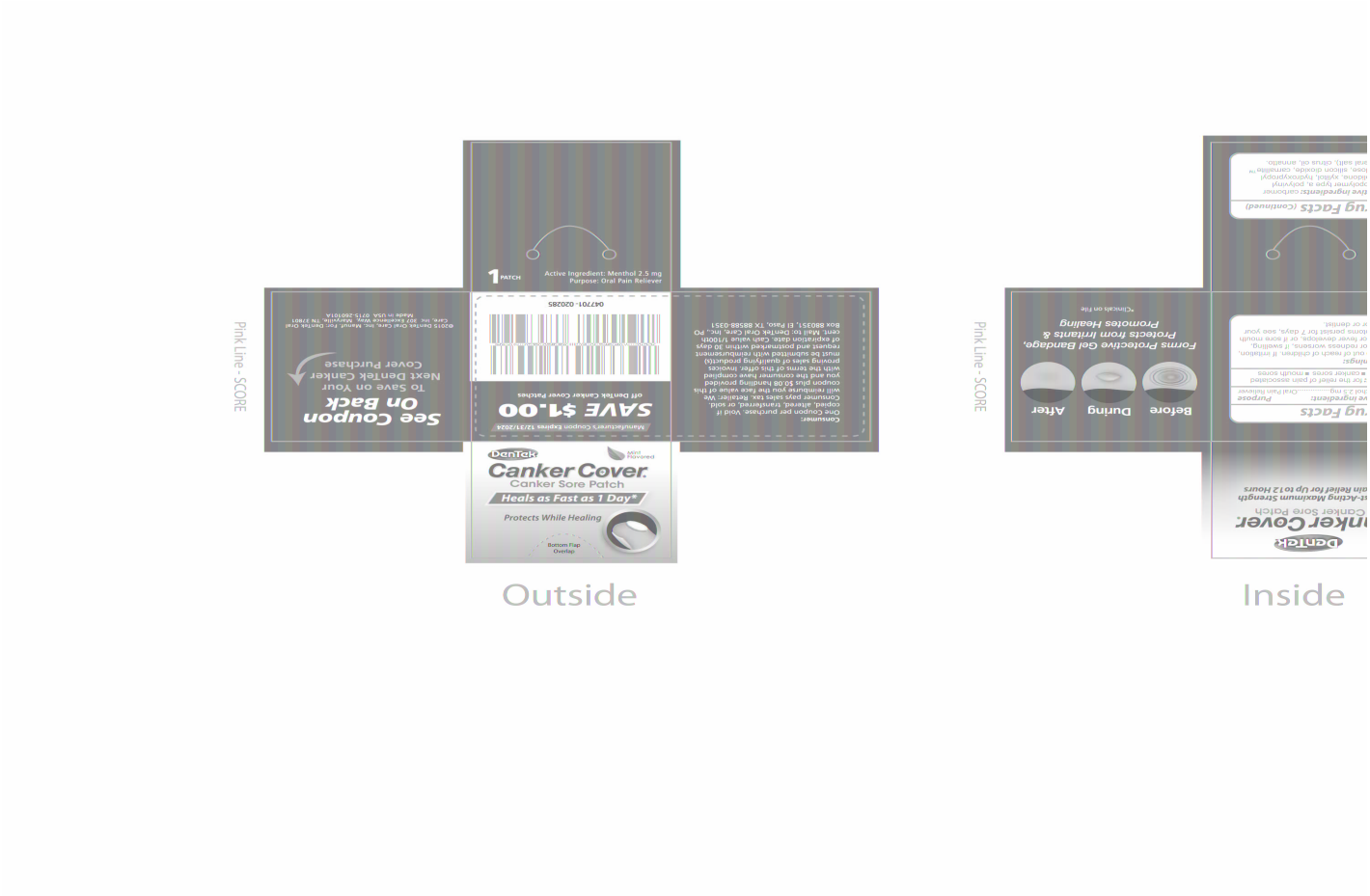
DENTEK CANKER COVER- menthol patch, extended release
DenTek Oral Care, Inc.

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.

Canker Cover 1 Count

Outer Packet Labeling



Active ingredient: (per each patch)

Menthol 2.5 mg

Purpose

Oral Pain Reliever

Uses: for the relief of pain associated with: **.** canker sores **.** mouth sores

Warnings:

Keep out of reach of children.

Warnings:

If irritation, pain or redness worsens, if swelling, rash or fever develops, or if sore mouth symptoms persist

for 7 days, see your doctor or dentist.

Directions for use:**adults and children 5 years of age and older**

The sore should be dry (pat with tissue) if 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 the patch before it dissolves.** Consult your dentist or doctor before using.

In case of discomfort, the patch may be removed by gently peeling it from the sides with your finger while

washing with warm water.

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Inactive ingredients: carbomer homopolymer type a, polyvinyl pyrrolidone, xylitol, hydroxypropyl cellulose, silicon dioxide, carmallite ™(mineral salt), citrus oil, annatto.

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**
SEA SALT (UNII: 87GE52P74G)	10 mg in 194.85 mg
CARBOMER 934 (UNII: Z135WT9208)	56 mg in 194.85 mg
POVIDONE (UNII: FZ989GH94E)	44 mg in 194.85 mg
XYLITOL (UNII: VCQ006KQ1E)	65 mg in 194.85 mg
HYDROXYPROPYL CELLULOSE (TYPE E) (UNII: 66O7AQV0RT)	14 mg in 194.85 mg
CITRUS MEDICA FRUIT (UNII: ZE5Q6PN9ON)	2 mg in 194.85 mg
COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	1.45 mg in 194.85 mg
MAGNESIUM STEARATE (UNII: 70097M6I30)	0.4 mg in 194.85 mg

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
	NDC:60630-091			

1	NDC:60630-091-04	1 in 1 PACKET	12/01/2015	
1	NDC:60630-091-01	2.5 mg in 1 DOSE PACK; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	11/11/2015	

Labeler - DenTek Oral Care, Inc. (153818646)

Registrant - DenTek Oral Care, Inc. (153818646)

Establishment

Name	Address	ID/FEI	Business Operations
DenTek Oral Care, Inc.		153818646	relabel(60630-091)

Revised: 12/2015 DenTek Oral Care, Inc.