

CANKERMELTS- benzocaine lozenge
Quest Products, LLC

CankerMelts®

Active Ingredient (in each self-adhering tablet)

Benzocaine 15mg

Purpose

Oral Pain Relief

Uses

for temporary relief of pain associated with:

- canker sores
- minor irritation
- mouth sores

Warnings

Methemoglobinemia warning:

Use of this product may cause methemoglobinemia, a serious- condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops:

- pale, gray, or blue colored skin (cyanosis)
- headache
- rapid heart rate
- shortness of breath
- dizziness or lightheadedness
- fatigue or lack of energy

Allergy alert:

Do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other "caine" anesthetics.

Do not use:

- this product for more than 7 days unless directed by a doctor or dentist
- in children under 5 years of age

When using this product

do not exceed recommended dosage.

Stop use and ask a doctor or dentist if:

- if sore mouth symptoms do not improve in 7 days
- if irritation, pain, or redness persists or worsens
- if swelling, rash or fever develops

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children

in case of overdose, get medical help or contact a Poison Control Center right away.

Directions**Adults and children age 5 and older:**

Affix one tablet as directed below and allow to slowly dissolve in the mouth. May be repeated every 2 hours as needed or directed by a doctor or dentist. This product may last over 2 hours.

Placement:

CankerMelts are bi-layered tablets with a dimple on the adhesive side and a pain reliever on the domed side marked CM. Place the adhesive side with a dimple against teeth or gums or braces or appliance. Place opposite or adjacent to the sore. Hold tablet in place with your cheek or tongue for 10 seconds to initiate adhesion. Adhesion will strengthen over the next few minutes. It may be removed at any time.

Children under 5 years of age:

Do not use.

Other Information

- Protect from humidity
- Store at 15°C - 30°C (59°F - 86°F)

Inactive Ingredients

Acacia gum, cellulose gum, hyaluronic acid, magnesium stearate, maize dextrin, methylcobalamin (vitamin B12), mint oil, sodium bicarbonate, xylitol

CankerMelts® 15mg carton of 20



CANKERMELTS

benzocaine lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68229-700
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	15 mg

Inactive Ingredients

Ingredient Name	Strength
HYALURONIC ACID (UNII: S270N0TRQY)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
XYLITOL (UNII: VCQ006KQ1E)	
METHYLCOBALAMIN (UNII: BR1SN1JS2W)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
ACACIA (UNII: 5C5403N26O)	

Product Characteristics				
Color	white (bi-layered; slightly pink/off-white)		Score	no score
Shape	ROUND		Size	12mm
Flavor			Imprint Code	CM
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68229-700-20	2 in 1 CARTON	10/06/2023	
1		10 in 1 BLISTER 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		10/06/2023	

Labeler -
Quest Products, LLC (075402441)

Establishment			
Name	Address	ID/FEI	Business Operations
Quest Products, LLC		116971363	manufacture(68229-700)