

RED CROSS CANKER SORE- benzocaine ointment

The Mentholatum Company

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.

Drug Facts

Active ingredient

Benzocaine 20%

Purpose

Oral anesthetic/analgesic

Uses

temporarily relieves pain and minor irritation of the mouth and gums due to ■ canker sores ■ minor dental procedures ■ braces ■ dentures

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

- for teething
- in children under 2 years of age

When using this product

- do not use for more than 7 days unless directed by a dentist or doctor
- do not exceed recommended dosage

Stop use and ask a doctor if

- sore mouth symptoms last more than 7 days
- irritation, pain, or redness persists or worsens
- swelling, rash, or fever develops

Keep Out of Reach of Children

If more than used for pain is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

- snip off tip of tube
- apply to affected area; carefully coat with a protective layer
- supervise children using this product
- adults and children 2 years and over: use up to 4 times daily or as directed by a doctor
- children under 2 years: do not use

Inactive Ingredients

aloe barbadensis leaf extract, butylated hydroxytoluene, carbomer homopolymer, cetylpyridinium chloride, chamomilla recutita (matricaria) flower extract, cocos nucifera (coconut) oil, commiphora myrrha resin, dimethicone, echinacea purpurea extract, flavor, glyceryl stearate, menthol, mineral oil, silica dimethicone silylate, vitamin E, white petrolatum

Package/Label Principal Display Panel



Principal Display Panel

RED CROSS CANKER SORE

benzocaine ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10742-8915
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
CHAMOMILE (UNII: FGL3685T2X)	
COCONUT OIL (UNII: Q9L0O73W7L)	
MYRRH (UNII: JC71GJ1F3L)	
ECHINACEA PURPUREA (UNII: QI7G114Y98)	
GLYCERYL 1-STEARATE (UNII: 258491E1RZ)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
MINERAL OIL (UNII: T5L8T28FGP)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10742-8915-1	1 in 1 BLISTER PACK	08/19/1998	
1		7 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	08/19/1998	

Labeler - The Mentholatum Company (002105757)

Registrant - The Mentholatum Company (002105757)

Establishment

Name	Address	ID/FEI	Business Operations
The Mentholatum Company		002105757	manufacture(10742-8915)