CAINETIPS- benzocaine liquid J MORITA USA 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.

J MORITA USA - CAINE TIPS (70769-101)

ACTIVE INGREDIENT

BENZOCAINE 20%

PURPOSE

PAIN RELIEVER

USES

For temporary relief of pain due to: minor dental procedures, minor mouth and/or gum irritation caused by dentures or orthodontic appliances, Vincent's infection, or canker sores.

WARNINGS

Do not use: if patient is allergic to local anesthetics such as procaine, butacaine, benzocaine, or other "caine" anesthetics;

exceeding recommended dosage for more than 7 days unless directed by a dentist; if sore mouth symptoms

do not improve in 7 days; if irritation, pain or redness persists or worsens; or if swelling, rash or fever develops, see a

dentist or a physician promptly.

If pregnant or breast feeding, ask a health professional before use.

Keep out of reach of children.

DIRECTIONS

HOLD WITH SOLID WHITE TIP STRAIGHT DOWN; BEND AND SNAP OPEN UPPER TIP AT COLORED RING; ALLOW MEDICINE TO FLOW DOWN.

APPLY PRODUCT TO INTENDED AREA; ALLOW IT TO REMAIN IN PLACE AT LEAST 1 MINUTE AND THEN REMOVE IT FROM MOUTH; DISPOSE AFTER APPLICATION.

USE UP TO 4 TIMES DAILY, OR AS DIRECTED BY A DENTIST. ADULT SUPERVISION REQUIRED FOR USE WITH CHILDREN UNDER 12 YEARS. CONSULT A DENTAL PROFESSIONAL FOR USE WITH CHILDREN UNDER 2 YEARS.

INACTIVE INGREDIENTS

ARTIFICIAL FLAVOR, POLYETHYLENE GLYCOL, ETHOXY DIGLYCOL

DRUG FACTS

Active Ingredient

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Purpose Pain reliever

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Do not use: if patient is allergic to local anesthetics such as procaine, butacaine, benzocaine, or other "caine" anesthetics; exceeding recommended dosage for more than 7 days unless directed by a dentist; if sore mouth symptoms do not improve in 7 days; if irritation, pain or redness persists or worsens; or if swelling, rash or fever develops, see a dentist or a physician promptly. **If pregnant or breast feeding, ask a health professional before use. Keep out of reach of children.**

Directions

Hold with solid white tip straight down; bend and snap open upper tip at colored ring; allow medicine to flow down. Apply product to intended area; allow it to remain in place at least 1 minute and then remove it from mouth; dispose after application. Use up to 4 times daily or as directed by a dentist. Adult supervision required for use with children under 12 years. Consult a dental professional for use with children under 2 years.

Inactive Ingredients

Artificial flavor, polyethylene glycol, ethoxy diglycol

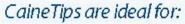
Patent # 5,702,035





Oral Pain Reliever

CaineTips offer easy to use, topical pain relief. Each individually wrapped disposable swab is pre-filled with a 20% benzocaine solution designed for intraoral applications. CaineTips are available in a delicious cherry flavor.



- · Pre-injection
- · Hygiene procedures, such as periodontal curettage, and deep scaling
- Pain relief due to ulcers, wounds, and other minor mouth irritations caused by dentures or orthodontic appliances
- +Dental procedures, such as impression and radiograph taking
- Pediatric dentistry: child friendly, easy to manage application, and reduced saliva reaction
- Post-care treatment

How To Use

1.

1. Hold with solid white tip straight down

3.Allow medicine to flow down

2. Bendland snap open upper tip at colored ring

2.

Box includes 100 individually wrapped swabs.







Product Demo Online: jmoritausa.com/cainetips

Features

- Convenient
- Pre-measured dosage
- Direct and precise application
- Quick pain relief onset
- Maximum strength
- · Disposable package
- · No mess, no drips
- · Easy to use
- · Delicious cherry flavor
- · Helps prevent cross-contamination

Solution colorized for illustration purposes)

Ordering Information Cherry Flavor (100 ct) 27-1100

To order or for a free sample call 888-JMORITA (566-7482) or contact your dealer.

J.MORITA

WWW.JMORITAUSA.COM

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benzocaine liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:70769-101

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5) BENZOCAINE 20 g in 100 mL

Inactive Ingredients

Ingredient Name Strength

POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)

DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70769- 101-51	100 in 1 BOX	06/06/2016	
1	NDC:70769- 101-11	0.15 mL in 1 APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing III	Harketing information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	06/06/2016		

Labeler - J MORITA USA INC (021866033)

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