

## **KANKA SOFTBRUSH- benzocaine and zinc chloride gel**

**Blis tex 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.*

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**KANKA®**

**SoftBrush**

### ***Drug Facts***

<b><i>Active ingredients</i></b>	<b><i>Purpose</i></b>
Benzocaine 20.0% (w/w)	Oral anesthetic/analgesic
Zinc Chloride 0.1% (w/w)	Oral astringent

### **Uses**

- for the temporary relief of pain due to toothaches, canker sores, minor irritation of the mouth and gums caused by dentures or orthodontic appliances, or minor injury of the mouth or gums

### **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 this product for more than 7 days unless directed by a dentist or doctor. 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 your dentist or doctor promptly.
- do not exceed recommended dosage.

**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**

- adults and children 2 years of age and older:

- twist base clockwise to dispense. It may take up to 10 full turns to dispense the initial dose, but subsequent uses should require less than 1 turn.
- to clean brush tip, rinse with cold water
- dry affected area and apply medication by gently brushing the affected area.
- use up to 4 times daily, or as directed by a dentist or doctor
- children under 12 years of age should be supervised in the use of this product
- children under 2 years of age: do not use

#### **Other information**

- do not purchase if package has been opened
- replace cap after use to prevent drying
- avoid contact with the eyes
- this is a personal care item, and should be used by one individual only
- with zinc chloride, some color may be evident; this is normal

#### **Inactive ingredients**

flavors, glycerin, PEG-8, PEG-75, phenoxyethanol, silica, sucralose

#### **PRINCIPAL DISPLAY PANEL - 2.0 g Applicator Blister Pack**

Blistex®

MAXIMUM STRENGTH

KANKA®

Soft Brush®

Tooth & Gum Pain Gel

ORAL ANESTHETIC/ASTRINGENT

Maximum Pain Relief

Dual Medications

Gentle Application

Easy Reach Design

Ultra Soft Tip

50+ Uses

Toothaches

Brace/Denture Irritation

Gum Discomfort

Canker Sores

Net Wt.

0.07 oz. (2.0 g)

**Blistex**

**MAXIMUM STRENGTH**

**KANK-A<sup>®</sup>**

*Soft Brush<sup>®</sup>*

*Tooth & Gum Pain Gel*

ORAL ANESTHETIC/ASTRINGENT

**Maximum Pain Relief**

**Dual Medications**

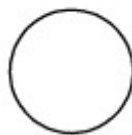
**Gentle Application**

Easy Reach Design • Ultra Soft Tip  
• 50+ Uses •

**Toothaches**  
Brace/Denture Irritation  
Gum Discomfort  
Canker Sores

Net Wt.  
0.07 oz (2.0 g)

**MAXIMUM STRENGTH**  
**KANKA**<sup>®</sup>  
 SoftBrush<sup>®</sup>  
 Tooth & Gum Pain Gel



Twist base to dispense

**Strong Relief With A Soft Touch<sup>®</sup>**

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Oral astringent

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SATISFACTION  
GUARANTEED

**Blistex**

Carton is 100% Recyclable.

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Oak Brook, IL 60522-5392 #C010163

### Drug Facts (continued)

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## KANKA SOFTBRUSH

benzocaine and zinc chloride gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10 157-2106
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 mg in 100 g
ZINC CHLORIDE (UNII: 86Q357L16B) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.1 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
GLYCERIN (UNII: PDC6A3C0OX)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10 157-2106-1	1 in 1 BLISTER PACK	09/25/2019	
1		2 g in 1 APPLICATOR; Type 0: Not a Combination Product		
2	NDC:10 157-2106-2	2 in 1 BLISTER PACK	09/25/2019	
2		2 g in 1 APPLICATOR; 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	09/25/2019	

**Labeler** - Blistex Inc (005126354)

## Establishment

Name	Address	ID/FEI	Business Operations
Blistex Inc		005126354	MANUFACTURE(10 157-2106)

Revised: 9/2019

Blistex Inc