

MOUTH SORE MEDICATION- benzocaine liquid

Zee Medical

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.

COMPARE TO THE ACTIVE INGREDIENT IN KANK-A®

ZEE MOUTH SORE MEDICATION

ORAL PAIN RELIEVER

Fast Mouth Sore Relief

- Canker sores
- Gum Pain
- Toothache
- Dental Work

25 Packets

0.5g (0.017 oz) per packet

DO NOT USE IF PACKET IS TORN OR OPEN

Drug Facts

Active ingredient

Benzocaine 20% (w/w)

Purpose

Oral pain reliever

Uses

temporarily relieves pain caused by

- toothache
- canker sores
- gum sores
- dental work
- cheek bites
- denture irritation
- minor irritation or injury of the mouth and gums

Warnings

For oral use only. Avoid contact with eyes.

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

When using this product do not use for more than 7 days unless directed by a dentist or doctor. If sore mouth symptoms do not improve e in 7 days; if irritation, pain or redness persists or worsens; or if swelling, rash or fever develops, see your doctor or dentist promptly. Do not exceed recommended dosage.

Keep out of reach of children. If more than used for pain relief is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 2 years and older: dry affected area and apply medication. Use up to 4 times daily, but not more than every 2 hours, 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: ask a dentist or doctor

Inactive ingredients

PEG 400, PEG 3350, peppermint oil, sodium saccharin, sorbic acid

Questions?

1-800-841-8417

Distributed by

Zee Medical, Inc., Irvine, CA 92606

This product is not manufactured or distributed by Blistex, Inc., distributor of KANK-A[®] Mouth Pain Liquid

PRINCIPAL DISPLAY PANEL – packet label

DO NOT USE IF PACKET IS TORN OR OPEN

MOUTH SORE ZEE

MEDICATION

Oral Pain Reliever

Fast Mouth Sore Relief

- Canker sores
- Gum Pain
- Toothache
- Dental Work

5g (0.017 oz)

DO NOT USE IF PACKET IS TORN OR OPEN

MOUTH SORE MEDICATION



Oral Pain Reliever

Fast Mouth Sore Relief

- Canker Sores
- Gum Pain
- Toothache
- Dental Work

0.5 g
(0.017 oz)

Active ingredient: Benzocaine 20% w/w (oral pain reliever)

Warnings: For oral use only. Do not use this product if you have a history of allergy to local anesthetics. If irritation, pain or redness lasts for 7 days or gets worse, or if swelling, rash or fever develops, see your doctor promptly. Do not exceed recommended dosage. **Keep out of reach of children.** If more than used for pain relief is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions: adults - dry affected area and apply medication. Use up to 4 times daily, but not more than every 2 hours.

For full label information see box or go to zeemedical.com.

PRINCIPAL DISPLAY PANEL – Carton label

NDC 35418-631-01

COMPARE TO THE ACTIVE INGREDIENT IN KANK-A®*

ZEE MOUTH SORE MEDICATION

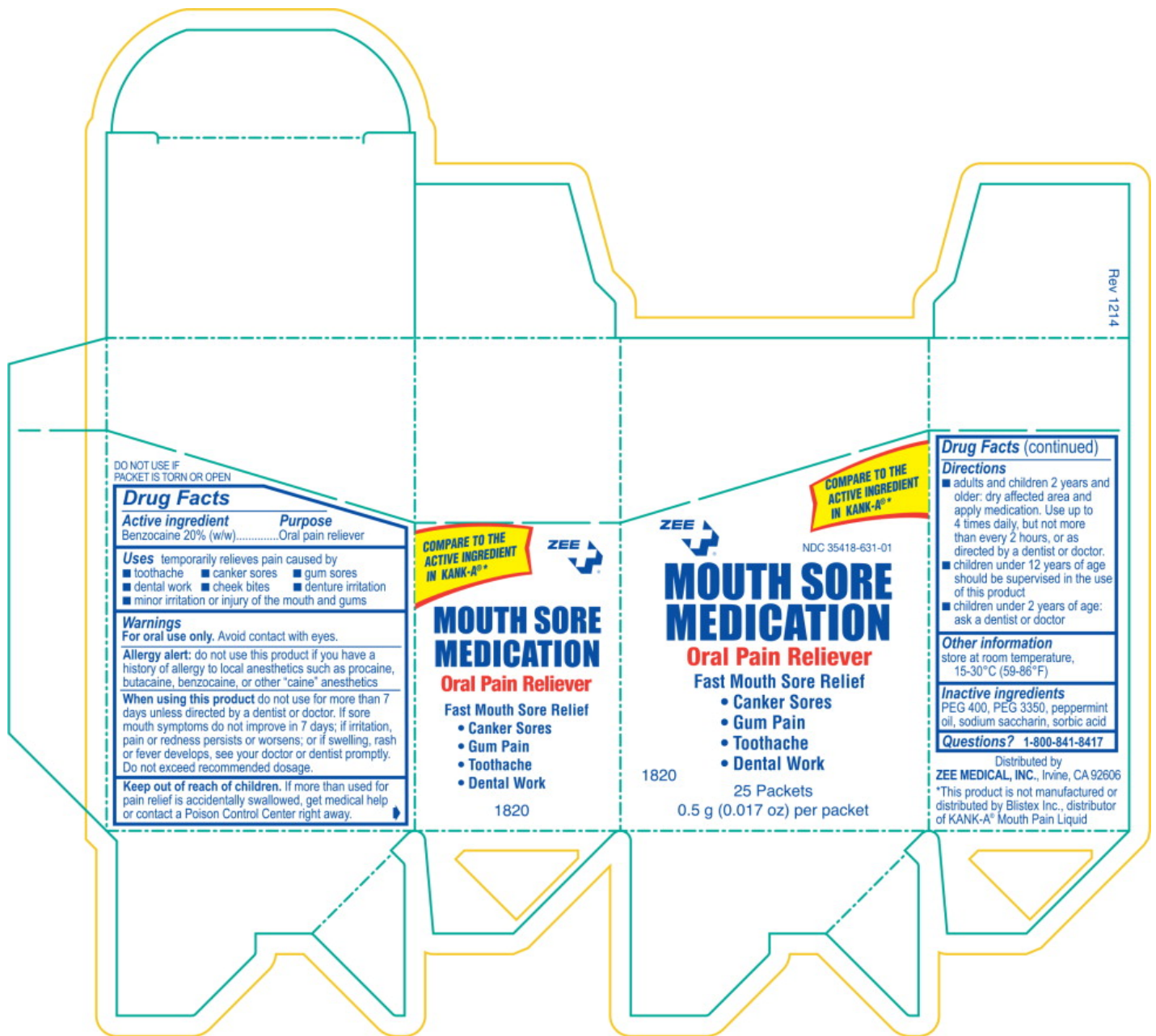
ORAL PAIN RELIEVER

Fast Mouth Sore Relief

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25 Packets

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MOUTH SORE MEDICATION

benzocaine liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:35418-631 |
| 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 |
|---|----------|
| polyethylene glycol 400 (UNII: B697894SGQ) | |
| polyethylene glycol 3350 (UNII: G2M7P15E5P) | |
| peppermint oil (UNII: AV092KU4JH) | |
| saccharin sodium dihydrate (UNII: SB8ZUX40TY) | |
| sorbic acid (UNII: X045WJ989B) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:35418-631-01 | 25 in 1 BOX | | |
| 1 | | 0.5 g in 1 PACKET; 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 | 05/01/2010 | |

Labeler - Zee Medical (009645623)

Registrant - Safetec of America, Inc. (874965262)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|------------------------|
| Safetec Of America, Inc. | | 874965262 | MANUFACTURE(35418-631) |

Revised: 6/2014

Zee Medical