# TANAC ORAL PAIN RELIEVER- benzocaine liquid Leosons Overseas Corp

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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#### **TANAC Oral Pain Reliever**

#### **Drug Facts**

#### **Active Ingredients & Purposes**

| Active Ingredient | Purpose            |
|-------------------|--------------------|
| Benzocaine 10%    | Oral pain reliever |

#### Uses

Temporarily relieves pain due to

- canker sores
- cold sores
- fever blisters
- minor irritations or injury of the mouth and gums

### Warnings

#### For oral use only.

**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. If a skin reaction occurs, stop use and seek medical help right away.

**Flammability warning:** Keep away from fire or flame.

#### Stop use and ask a doctor or dentist if

- sore mouth symptoms do not improve in 7 days
- symptoms clear up and occur again within a few days
- irritation, pain or redness persists or worsens swelling, rash, or fever develops

#### If pregnant or breast-feeding,

ask a health professional before use.

#### Do not use

- for teething
- in children under 2 years of age

#### When using this product

- avoid contact with the eyes
- do not use more than directed
- do not use for more than 7 days unless directed by a dentist or doctor

#### Keep out of reach of children.

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

#### **Directions**

- apply product with cotton swab or clean fingertip to the affected area
- adults and children 2 years of age and older: use up times 4 times daily or as directed by a

dentist or doctor. Children should be supervised in the use of this product.

• children under 2 years of age: do not use

#### Other information

- store at 20 25°C (68 77°F)
- do not use if imprinted safety seal is torn, broken or missing prior to opening
- keep carton for full drug facts

#### **Inactive ingredients**

benzalkonium chloride, peppermint oil, polyethylene glycol 400, propylene glycol, sodium saccharin, tannic acid

#### Questions?

**1-855-452-9500** or email at info@leosonsintl.com

#### **Principal Display Panel**

- canker sores
- gum irritations
- cold sores
- fever blisters

Tanac ®

Benzocaine 10%

**Oral Pain Reliever** 

NO STING LIQUID

0.45 FL Oz. (13.3mL)



- Canker Sores Gum Irritations
- Cold Sores
  Fever Blisters Benzocaine 10% Oral Pain Reliever

SAFETY SEALED BOTTLE CAP



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#### TANAC ORAL PAIN RELIEVER

benzocaine liquid

**Product Information** 

| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:69626-0049 |
|-------------------------|----------------|--------------------|----------------|
| Route of Administration | ORAL           |                    |                |

| Active Ingredient/Active Moiety                                     |                   |                |
|---|-------------------|----------------|
| Ingredient Name   | Basis of Strength | Strength       |
| BENZO CAINE (UNII: U3RS Y48 JW5) (BENZO CAINE - UNII: U3RS Y48 JW5) | BENZOCAINE        | 10 g in 100 mL |

| Inactive Ingredients                       |          |  |
|--|----------|--|
| Ingredient Name                            | Strength |  |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY)        |          |  |
| TANNIC ACID (UNII: 28F9E0DJY6)             |          |  |
| PEPPERMINT OIL (UNII: AV092KU4JH)          |          |  |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)        |          |  |
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)   |          |  |
| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) |          |  |

|   | Packaging          |  |                             |                    |
|---|--------------------|--|-----------------------------|--------------------|
| ı | # Item Code        | Package Description                                    | <b>Marketing Start Date</b> | Marketing End Date |
| ı | 1 NDC:69626-0049-4 | 1 in 1 CARTON  | 0 1/0 1/20 15               |                    |
| l | 1                  | 13.3 mL in 1 BOTTLE; 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                                  | 0 1/0 1/20 15        |                    |
|                         |  |                      |                    |

## Labeler - Leosons Overseas Corp (148605470)

Revised: 12/2020 Leosons Overseas Corp