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.

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)

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**
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	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

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69626-0049-4	1 in 1 CARTON	01/01/2015	
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	01/01/2015	

Labeler - Leosons Overseas Corp (148605470)

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