THERACARE MAXIMUM STRENGTH ORAL PAIN RELIEF SEVERE- benzocaine 20%, benzalkonium chloride 1% gel
Veridian Healthcare

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.

TheraCare Maximum Strength Oral Pain Relief

Active ingredients

Benzocaine 20%

Benzalkonium Chloride 0.1%

Purpose

Oral pain reliever

Antiseptic

Use

- for the temporary relief of pain due to toothaches
- to help protect against infection in minor oral irritation

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

- more than directed
- for more than 7 days unless directed by a physician or healthcare provider

Stop use and ask a physician if

- swelling, rash or fever develops
- irritation, pain or redness persists or worsens
- symptoms do not improve in 7 days

KEEP OUT OF REACH OF CHILDREN:

In case of overdose or allergic reaction, get medical help or contact a Poison Control Center right away (1-800-222-1222)

Directions

- **Adults and children 2 years of age and over -** Apply a small amount of product to the cavity and around the gum surrounding the teeth. Use up to 4 times daily or as directed by a physician or healthcare provider
- **Children under 12 years of age -** Should be supervised in the use of this product
- **Children under 2 years of age** - Ask a physician or healthcare provider

Other information

- this preparation is intended for use in cases of toothache, only as a temporary expedient until a physician can be consulted
- do not use continuously
- avoid using toothpaste or drinking soft drinks or fruit juices for at least one hour after applying
- do not use if tube seal under cap is broken
- store at 20-25C (68-77F)

Inactive ingredients

Glycerin, polyethylene glycol, saccharin sodium, sodium polyacrylate, sorbic acid, sorbitol, strawberry furanone, water.

Questions or comments?

TOLL FREE **866-326-1313** M-F 8:30 am-4:30 pm CST

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benzocaine 20%, benzalkonium chloride 1% gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71101-201
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
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHYLHYDROXY FURANONE (UNII: 20PI8YZP7A)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBIC ACID (UNII: X045WJ989B)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71101-201-01	1 in 1 CARTON	02/01/2022	
1		9.35 g in 1 TUBE; 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	02/01/2022	

Labeler - Veridian Healthcare (830437997)

Establishment

Name	Address	ID/FEI	Business Operations
ANICARE PHARMACEUTICALS PRIVATE LIMITED		916837425	manufacture(71101-201)

Revised: 10/2022 Veridian Healthcare