

**ASTONEA MAXIMUM STRENGTH ORAL PAIN RELIEF- benzocaine 20%,  
benzalkonium chloride 1% gel  
ASTONEA LABS PRIVATE LIMITED**

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**ASTONEA 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**

aloe vera leaf, butylated hydroxytoluene, carbomer, cetyl alcohol, cholecalciferol, edetate disodium anhydrous, ethylhexylglycerin & phenoxyethanol, glycerol monostearate, isopropyl myristate, isopropyl palmitate, isopropyl stearate, light mineral oil, PEG 100 stearate, PEG 4000, propylene glycol, sodium benzoate, sodium hydroxide, sodium laureth sulfate, sodium metabisulfite, sodium sulfite, vitamin A palmitate, vitamin E, water

**PAIN RELIEF  
FORMULA**

**Maximum Strength  
Oral Pain Relief Gel**

BENZOCAINE 20% + BENZALKONIUM CHLORIDE 1%

**Drug Facts**

**Active ingredients** Purpose  
Benzocaine 20% ..... Oral pain reliever  
Benzalkonium chloride 0.1% ..... Antiseptic

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

**Warnings**  
Methemoglobinemia is a 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: a 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 ■ for soothing ■ in children under 2 years of age

**Drug Facts (continued)**

Stop use and ask a doctor 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 over 2 years: apply a small amount of product to the cavity and around gum surrounding the tooth. 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: do not use.

**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 or seal under cap is broken ■ store at 20°-25°C (68°-77°F)

**Inactive ingredients:** glycerin, polyethylene glycol, saccharin sodium, sodium polyacrylate, sorbic acid, sorbitol, strawberry flavoring, water



Manufactured for:  
Vention Healthcare, LLC  
117 S. Lakeside Drive  
Germantown, IL 60031 USA  
www.ventionhealthcare.com  
Made in India  
Customer Care Help Line  
**866-326-1313**  
Mon-Fri 8:00 am-5:00 pm CST  
921942 10/22 Y CST 0002  
02022 Vention Healthcare, LLC

LOT  
EXP

NET WT .33 OZ (9.35g)



**Maximum Strength  
Oral Pain Relief Gel**

BENZOCAINE 20% + BENZALKONIUM CHLORIDE 0.1%

NDC 71101-201-01

**FAST-ACTING  
PAIN RELIEF**



**2X Medicated**  
for Toothache Pain Relief & Infection Protection

STRAWBERRY GEL

**ASTONEA MAXIMUM STRENGTH ORAL PAIN RELIEF**

benzocaine 20%, benzalkonium chloride 1% gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77338-201
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>BENZOCAINE</b> (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 g
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	10 mg in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>ISOPROPYL MYRISTATE</b> (UNII: ORE8K4LNJS)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>ISOPROPYL PALMITATE</b> (UNII: 8CRQ2TH63M)	
<b>ISOPROPYL STEARATE</b> (UNII: 43253ZW1MZ)	
<b>WATER</b> (UNII: 059QF0KOOR)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77338-201-01	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 Drug	M013	02/01/2022	

**Labeler** - ASTONEA LABS PRIVATE LIMITED (878533295)