ULTRACARE ORAL ANESTHETIC WALTERBERRY- benzocaine gel
Ultradent Products, Inc.

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.

Ultracare® Oral Anesthetic Walterberry®

Drug Facts

Active Ingredient

Benzocaine 20% w/v

Purpose

Oral Anesthetic

Uses

For the temporary relief of occasional minor irritation and pain associated with

- minor dental procedures
- sore mouth and throat
- minor injury of the gums
- canker sores
- minor irritation of the mouth or gums caused by dentures or orthodontic appliances.

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.

For external use only

Allergy alert

Do not use if you have a history of allergy to local anesthetics such as procaine,

butacaine, benzocaine or other "caine" anesthetics, PABA compounds, or sunscreen. If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning

if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persist or worsens, see your dentist or doctor promptly.

Do not use

- if taking sulfonamides
- for teething
- in children under 2 years of age

When using this product

- avoid contact with eyes.

Keep out of reach of children. in case of overdose, get medical help or contact a Poison Control Center right away. Do not exceed recommended dosage.

Directions

Adults and children 2 years of age and older: Apply a thin film to affected area. Allow to remain in place at least 1 minute and then spit out. Use up to 4 times daily or as directed by your dentist or doctor.

- **Children between 2 and 12 years of age:** Should be supervised in the use of this product.
- **Children under 2 years of age:** Do not use.

Other information

- Phenylketonurics: Contains Phenylalanine 3 mg per gram
- Do not use if tamper-evident seal is broken
- Store at room temperature

Inactive ingredients

aspartame, D&C red no. 28, ethyl alcohol, FD&C red no. 40, glycerin, natural and artificial flavors, polyethylene glycol, sodium saccharin

Questions or comments?

800.552.5512

Manufactured by Ultradent Products, Inc.
505 West Ultradent Drive (10200 South), South Jordan, UT 84095

Ultracare®
ORAL ANESTHETIC GEL

Description:

Ultracare is a 20% w/v (17.9%) benzocaine oral anesthetic gel preparation in a water-soluble glycol base. Ultracare is designed for rapid onset (10-30 seconds). Anesthesia usually lasts 8-10 minutes. Ultracare is NOT for injection.

Uses:

For the temporary relief of occasional minor irritation and pain, associated with:

- Minor dental procedures
- Sore mouth and throat
- Minor injury of the gums
- Canker sores
- Minor irritation of the mouth or gums caused by dentures or orthodontic appliances

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.

For external use only

Allergy alert:

Do not use if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics, PABA compounds, or sunscreen. If a skin reaction occurs, stop use and seek medical help right away.

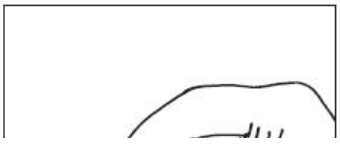
Sore throat warning:

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persist or worsens, see your dentist or doctor promptly.

Procedure:

1. Preloaded 1.2ml syringes:

    a. Remove luer lock cap from syringe.



b. Attach a Blue Micro® 20-gauge Tip or 5mm Micro Capillary Tip securely onto syringe.
c. Slowly express gel to the target tissue.
d. For anesthetizing periodontal pockets:

    i. Slowly apply a small amount to one quadrant at a time to the gingival margin or directly into the periodontal pockets and proceed with sub-gingival scaling.

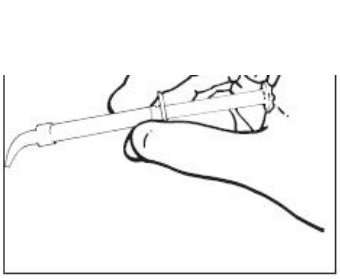


Fig. 1 Hold plunger in palm of hand for optimum control.

2. IndiSpense® delivery:

a. Remove cap from IndiSpense syringe.
b. Express desired amount of anesthetic to cotton applicator (Fig. 2) or into a dappen dish. Use a clean applicator with each area application. Re-cap the IndiSpense syringe after each use.
c. Using a dappen dish allows for re-application with the same applicator without the risk of cross-contamination. Re-cap the IndiSpense syringe after each use.

Fig. 2 Deliver Ultracare from the large, no-waste IndiSpense syringe to cotton applicator, cotton roll, etc., for placement.

3. IndiSpense delivery to empty 1.2ml syringe:

a. Attach a 1.2ml syringe to the end of IndiSpense by turning the luer lock of the 1.2ml syringe snugly onto male thread of Indispense syringe.
b. With palm, press plunger of IndiSpense syringe gently while guiding the 1.2ml plunger outward to desired fill.
c. RE-cap the IndiSpense syringe after each use.
d. See instruction for 1.2ml syringe use.

Directions:

Adults and children 2 years of age and older:

- Apply a thin film to affected area. Allow to remain in place at least 1 minute and then spit out. Use up to 4 times daily or as directed by your dentist or doctor.
- Rinse and expectorate to clear the oral cavity of residual product.
- Apply a thin film to injection site(s) allowing the gelled cotton applicator to remain in place at least 1 minute.
- Rinse and suction the oral cavity and continue with administering local anesthetic or with dental procedure.

For anesthetizing periodontal pockets:

- See instruction for 1.2ml use.

Children between 2 and 12 years of age:

- Should be supervised in the use of this product

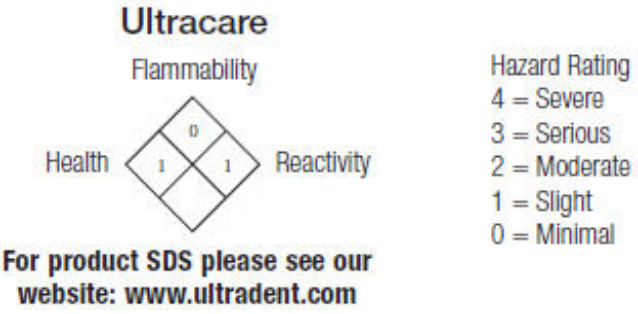
Children under 2 years of age:

- Do not use

Warnings and Precautions:

1. For Professional use only.
2. For external use only.
3. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.
4. Ultracare is NOT for injection.
5. Pregnancy and Lactation: Safety is not known in pregnancy/nursing women.
6. Avoid contact with eyes.
7. If applying intraorally from a syringe, verify flow on a gauze pad or mixing pad prior to applying. If resistance is met, replace tip and re-check.
8. If an excessive amount of gel is swallowed, get medical help or contact a Poison Control Center immediately.
9. Do not exceed maximum recommended dosage.
10. Phenylketonurics: Contains Phenylalanine—3mg per gram
11. See state or country guidelines for proper disposal of empty jar, syringes, applicator and tips.
12. To avoid cross-contamination of the prefilled syringes, use a disposable syringe cover, re-cap, and wipe syringe with an intermediate disinfectant between uses. If these measures are not taken, the syringes should be considered single-use. Tips are disposable. To avoid cross-contamination, do not re-use tips.

For immediate reorder and/or complete descriptions of Ultradent's product line, refer to Ultradent's catalog or call Toll Free: 1-800-552-5512.
Outside U.S. call (801) 572-4200.

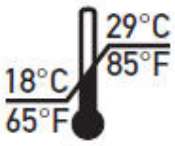


All Ultradent syringes have an expiration date stamped on the side of the syringe consisting of one letter and three numbers. The letter is a lot number used for manufacturing purposes and the three numbers are the expiration date. The first two numbers are the month, and the third number is the last number of the year.

Key:


Use by date


See Instructions



Store at room temperature


Keep out of reach of children


EN - Health hazard


Do not re-use to avoid cross contamination

Lot Number

Catalog Number

For Professional Use Only

Manufactured by Ultradent Products, Inc. 505 West Ultradent Drive, (10200 South) South Jordan, UT 84095 10057.18 052318

PRINCIPAL DISPLAY PANEL - 30 mL Syringe Label

Ultracare®
Oral Anesthetic Gel

Walterberry®

REF/UP 359

ULTRADENT
PRODUCTS, INC.

1.01 FL OZ (30 mL) IndiSpense®

Made in USA | 33325.15 061318

PEEL HERE

Ultracare®
Oral Anesthetic Gel

Walterberry®
REF/UP 359
ULTRADENT PRODUCTS, INC.
1.01 FL OZ (30 mL) IndiSpense®
Made in USA | 33325.16 062518

Drug Facts

Active ingredient — **Purpose**
Benzocaine 20% w/v ..... Oral Anesthetic

Uses For the temporary relief of occasional minor irritation and pain associated with • minor dental procedures • sore mouth and throat • minor injury of the gums • canker sores • minor irritation of the mouth or gums caused by dentures or orthodontic appliances.

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. ➤

Drug Facts (continued)

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.
For external use only

Allergy alert: Do not use if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics, PABA compounds, or sunscreen. If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persist or worsens, see your dentist or doctor promptly. ➤

ULTRACARE ORAL ANESTHETIC WALTERBERRY

benzocaine gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51206-202
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Benzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5)	Benzocaine	200 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Polyethylene Glycol, Unspecified (UNII: 3WQ0SDW1A)	
Glycerin (UNII: PDC6A3C0OX)	
Aspartame (UNII: Z0H242BBR1)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
Alcohol (UNII: 3K9958V90M)	
FD&C Red NO. 40 (UNII: WZB9127XOA)	
D&C Red NO. 28 (UNII: 767IP0Y5NH)	

Product Characteristics			
Color	RED (Dark red)	**Score**	
Shape		**Size**	
Flavor	BERRY (Walterberry)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51206-202-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/1993	01/08/2023
2	NDC:51206-202-02	1 in 1 BOX	06/01/1993	12/31/2024
2		30 mL in 1 SYRINGE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:51206-202-03	20 in 1 PACKAGE	06/01/1993	12/31/2024
3		1.2 mL in 1 SYRINGE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:51206-202-04	50 in 1 BAG	06/01/1993	07/31/2024
4		0.4 mL in 1 SYRINGE, PLASTIC; Type 0: Not a Combination Product		
5	NDC:51206-202-05	1 in 1 BAG	06/01/1993	12/31/2024
5		0.4 mL in 1 SYRINGE, PLASTIC; 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	06/01/1993	12/31/2024

Labeler - Ultradent Products, Inc. (013369913)

Establishment

Name	Address	ID/FEI	Business Operations
Ultradent Products, Inc.		013369913	MANUFACTURE(51206-202) , ANALYSIS(51206-202) , LABEL(51206-202) , PACK(51206-202)

Revised: 4/2021 Ultradent Products, Inc.