Benzocaine

Benzocaine Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 132 K) This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredients. Notes Text in parentheses is additional optional information which can be included on the PLA and product label at the applicant's discretion. The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant. Date March 19, 2021 Proper name(s), Common name(s), Source information Table 1. Proper name(s), Common name(s), Source information Proper name(s) Common name(s) Source information Source ingredient(s) 4-Aminobenzoic acid, ethyl ester Benzocaine Benzocaine References: Proper name: Merck 2012; Common name: Merck 2012, USP 35 2012, CTFA 2008; Source information: Merck 2012, CTFA 2008. Route(s) of administration Buccal Dental Gingival Oral Oromucosal Periodontal Topical Dosage form(s) This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document. The following dosage forms are acceptable when used according to the requirements indicated in this monograph: Aerosol, spray; Cream; Film-forming gel; Gargle; Gel; Gingival gel; Gingival paste; Liquid; Lozenge (oral only); Mouthwash; Ointment; Solution; Spray. Note Dosage forms must be acceptable for the specified route of administration. Use(s) or Purpose(s) Buccal/Oromucosal For the temporary relief of occasional minor oral irritation/oral pain/sore mouth (US FDA 1991). For the temporary relief of pain associated with canker sores/aphthous stomatitis (USP DI 2006; US FDA 1991) For the temporary relief of pain associated with cold sores/fever blisters/oral herpes (USP DI 2006; CPhA 1996). For the temporary relief of occasional minor irritation or injury of the mouth (US FDA 1991). For the temporary relief of pain due to minor irritation of the mouth due to dentures or orthodontic appliances (US FDA 1991). Dental For the temporary relief of pain arising as a result of toothache (US FDA 1991). Oral For the temporary relief of (pain of) sore throat (US FDA 1991). Periodontal/Gingival For the temporary relief of occasional minor irritation or injury of the gums (US FDA 1991). For the temporary relief of pain due to minor dental procedures (US FDA 1991). For the temporary relief of pain due to minor irritation of the gums due to dentures or orthodontic appliances (US FDA 1991). Topical For the temporary relief of pain associated with cold sores/fever blisters/oral herpes (USP DI 2006; CPhA 1996). Dose(s) Subpopulation(s) Gingival paste; Film-forming gel; Gargle; Lozenge; Mouthwash Children, Adolescents and Adults 6 years and older Aerosol, spray; Cream; Gel; Gingival gel; Liquid; Ointment; Solution; Spray Children, Adolescents and Adults 2 years and older Quantity(ies) Lozenge 2 - 15 milligrams of Benzocaine, per single dose; 1 to 6 times, per day (USP DI 2006; US FDA 1991) Aerosol, spray; Cream; Film-forming gel; Gargle; Gel; Gingival gel; Gingival paste; Liquid; Mouthwash; Ointment; Solution; Spray 5 - 20% of Benzocaine (US FDA 1991) Directions for use All products Use smallest amount possible to achieve desired result. Children under 12 years of age should be supervised by an adult in the use of this product (US FDA 1991). Do not eat for one hour following use (USP DI 2006; CPhA 1996). Do not chew gum or food while numbness persists (USP DI 2006; CPhA 1996). All products except for lozenge Avoid contact with eyes. Immediately flush thoroughly with water if contact occurs. Products for relief of sore throat Gargle Gargle for at least one minute and then spit out. Use up to four times daily or as directed by a dentist or another health care practitioner/health care provider/health care professional/doctor/physician (US FDA 1991). Lozenge Allow product to dissolve slowly in the mouth. Do not bite, chew or swallow whole. May be repeated every two hours as needed or as directed by a dentist or another health care practitioner/health care provider/health care professional/doctor/physician (USP DI 2006; US FDA 1991). Aerosol, spray; Spray Spray on the affected area for one second or less up to four times daily (US FDA 1991). Avoid inhaling (USP DI 2006). Use only when specifically directed by a dentist or another health care practitioner/health care provider/health care professional/doctor/physician (USP DI 2006). Products for relief of dental appliance pain Cream; Gel; Gingival gel; Liquid; Ointment; Solution Apply to the affected area, wait until relief is obtained, and rinse the mouth before reinserting the appliance (USP DI 2006). Contact a dentist at regular intervals when using this product to relieve pain during adjustment of new dentures or other dental appliances (USP DI 2006). All products except

for products for the relief of dental appliance pain and sore throat Aerosol, spray; Spray Spray on the affected area for one second or less up to four times daily (US FDA 1991). Avoid inhaling (USP DI 2006). Use only when specifically directed by a dentist or another health care practitioner/health care provider/health care professional/doctor/physician (USP DI 2006). Cream; Gel; Gingival gel; Liquid; Ointment; Solution Apply to the affected area up to four times daily with cotton, cotton applicator/swab or a fingertip or as directed by a dentist or another health care practitioner/health care provider/health care professional/doctor/physician (USP DI 2006). Gingival paste Dab small amounts as needed onto the affected area with cotton applicator/swab, avoiding rubbing or spreading, to prevent crumbling or grittiness (USP DI 2006) Film-Forming gels Dry the affected area with one of the swabs provided (USP DI 2006). Apply gel to a second swab and roll over the affected area (USP DI 2006). Keep mouth open and dry for 30 to 60 seconds after applying while film forms (USP DI 2006). Do not remove film which will slowly disintegrate over six hours (USP DI 2006). Apply up to four times a day or as directed by a dentist or another health care practitioner/health care provider/health care professional/doctor/physician (USP DI 2006). Mouthwash Swish around in the mouth, or allow to remain in place for at least one minute and then spit out. Use up to four times daily or as directed by a dentist or another health care practitioner/health care provider/health care professional/doctor/physician (US FDA 1991). Duration(s) of use All products For occasional use only. Risk information Caution(s) and warning(s) All products Keep out of reach of children. All products except topical products and products for relief of sore throat Consult your dentist or another health care practitioner/health care provider/health care professional/doctor/physician promptly if symptoms do not improve within seven days, irritation, pain or redness persists or worsens, or swelling, rash or fever develops (USP DI 2006; US FDA 1991). Products for relief of sore throat Consult a health care practitioner/health care provider/health care professional/doctor/physician promptly if sore throat is severe, persists for more than two days, or is accompanied by or followed by other symptoms such as fever, headache, rash, swelling, nausea, or vomiting (Pray 2006; USP DI 2006; US FDA 1991). Contraindication(s) All products Stop use and consult a health care practitioner/health care provider/health care professional/doctor/physician if the following symptoms appear: weakness, confusion, headache, difficulty breathing and/or pale, gray or blue coloured skin. These symptoms may be signs of methemoglobinemia, a rare disorder, which may appear up to 2 hours after use (US FDA 2018; HC 2011a,b; US FDA 2011, 2006). Do not use this product if you are allergic to benzocaine (HC 2011a,b; US FDA 1991). Known adverse reaction(s) All products Stop use if hypersensitivity/allergy occurs (HC 2011a;b US FDA 1991). Non-medicinal ingredients Must be chosen from the current Natural Health Products Ingredients Database(NHPID) and must meet the limitations outlined in the database. Storage conditions Store in airtight container. Protect from light (Martindale 2010). Store between 15-30ºC (USP DI 2006). Specifications The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide. The medicinal ingredient must comply with the requirements outlined in the NHPID. References cited CPhA 1996: Carruthers-Czyzewski P, Gillis C, Letwin D, editors. Nonprescription Drug Reference for Health Professionals. Ottawa (ON): Canadian Pharmaceutical Association; 1996. CTFA 2008: Gottschalck TE, Bailey JE, editors. International Cosmetic Ingredient Dictionary and Handbook. 12th edition. Washington (DC): The Cosmetic, Toiletry and Fragrance Association; 2008. HC 2011a: Health Canada 2011. Health risks associated with the use of topical benzocaine products. Internal document. Available on Request. HC 2011b: Health Canada advises Canadians of health risks involved with using benzocaine products. About Health Canada. [Accessed 2019 June 24]. Available from: https://www.canada.ca/en/news/archive/2006/11/health-canada-advises-canadians-health-risks-involved-using-benzocaine.html Martindale 2010: Sweetman SC, editor. Martindale: The Complete Drug Reference. 37th edition [Internet]. London (GB): Pharmaceutical Press; 2010. Benzocaine: ethyl 4-aminobenzoate, CAS: 94-09-7, 20101127. [Accessed 2019 June 24]. Available from: http://ovidsp.tx.ovid.com/ Merck 2012: O'Neil MJ, Heckelman PE, Koch CB, Roman KJ, editors. The Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals (14th Edition - Version 14.9). Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.; 2006, 2012. [Accessed 2019 June 24]. Available from: http://www.knovel.com/ US FDA 2018: FDA Drug Safety Communication: Risk of serious and potentially fatal blood disorder prompts FDA action on oral over-the-counter benzocaine products used for teething and mouth pain and prescription local anesthetics 05-23-2018. [Internet]. [Accessed 2019 June 24]. Available from: https://www.fda.gov/drugs/drug-safety-and-availability/risk-serious-and-potentially-fatal-blood-disorder-prompts-fda-action-oral-over-counter-benzocaine US FDA 2011: Benzocaine Topical Products: Sprays, Gels and Liquids - Risk of Methemoglobinemia. [Posted 04/07/2011] U.S. Food and Drug Administration MedWatch The FDA Safety Information and Adverse Event Reporting Program. [Internet]. [Accessed 2019 June 24]. Available from: https://wayback.archive-it.org/7993/20170112165108/http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm250264.htm US FDA 1991: US Department of Health and Human Services, Food and Drug Administration. 21 CFR Parts 356 and 369. [Docket No. 81N-0033]. Oral Health Care Drug Products for Over- the-Counter Human Use; Amendment to Tentative Final Monograph to Include OTC

Relief of Oral Discomfort Drug Products. ACTION: Notice of proposed rulemaking. [Internet]. Federal Register, Volume 56, Number 185, September 24, 1991. FR Citation: 56FR48302 [Accessed 2019 June 24]. Available from: https://www.fda.gov/drugs/status-otc-rulemakings/rulemaking-history-otc-oral-healthcare-drug-products USP DI 2006: Drug Information for the Health Care Professional. 26th edition, Volume 1. Greenwood Village (CO): Thomson Micromedex; 2006. References reviewed Abu-Laban RB, Zed PJ, Purssell RA, Evans KG. Severe methemoglobinemia from topical anesthetic spray: case report, discussion and qualitative systematic review. Canadian Journal of Emergency Medicine 2001;3(1):51-56. AHFS DI 2010: AHFS Drug Information 2010. Snow EK, editior. Bethesda (MD): American Society of Health-System Pharmacists; 2010. APA 2002: Berardi RR, DeSimone EM, Newton GD, Oszko MA, Popovich NG, Rollins CJ, Shimp LA, Tietze KJ, editors. 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MEDICINAL INGREDIENT(S)

Notes Text in parentheses is additional optional information which can be included on thePLAand product label at the applicant's discretion.The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant. Date March 19, 2021 Proper name(s), Common name(s), Source information Table 1. Proper name(s), Common name(s), Source informationProper name(s)Common name(s)Source informationSource ingredient(s)4-Aminobenzoic acid, ethyl esterBenzocaineBenzocaine

DOSAGE FORM(S)

The following dosage forms are acceptable when used according to the requirements indicated in this monograph: Aerosol, spray; Cream; Film-forming gel; Gargle; Gel; Gingival gel; Gingival paste; Liquid; Lozenge (oral only); Mouthwash; Ointment; Solution; Spray. Note Dosage forms must be acceptable for the specified route of administration.

RISK INFORMATION

Caution(s) and warning(s) All products Keep out of reach of children. All products except topical products and products for relief of sore throat Consult your dentist or another health care practitioner/health care provider/health care professional/doctor/physician promptly if symptoms do not improve within seven days, irritation, pain or redness persists or worsens, or swelling, rash or fever develops (USP DI 2006; US FDA 1991). Products for relief of sore throat Consult a health care practitioner/health care provider/health care professional/doctor/physician promptly if sore throat is severe, persists for more than two days, or is accompanied by or followed by other symptoms such as fever, headache, rash, swelling, nausea, or vomiting (Pray 2006; USP DI 2006; US FDA 1991). Contraindication(s) All products Stop use and consult a health care practitioner/health care provider/health care professional/doctor/physician if the following symptoms appear: weakness, confusion, headache, difficulty breathing and/or pale, gray or blue coloured skin. These symptoms may be signs of methemoglobinemia, a rare disorder, which may appear up to 2 hours after use (US FDA 2018; HC 2011a,b; US FDA 2011, 2006).Do not use this product if you are allergic to benzocaine (HC 2011a,b; US FDA 1991). Known adverse reaction(s) All products Stop use if hypersensitivity/allergy occurs (HC 2011a;b US FDA 1991).

NON-MEDICINAL INGREDIENTS

Must be chosen from the current Natural Health Products Ingredients Database(NHPID) and must meet the limitations outlined in the database. Storage conditions Store in airtight container. Protect from light (Martindale 2010).Store between 15-30ºC (USP DI 2006).

STORAGE CONDITION(S)

Store in airtight container. Protect from light (Martindale 2010).Store between 15-30ºC (USP DI 2006).

SPECIFICATIONS

The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.The medicinal ingredient must comply with the requirements outlined in the NHPID.

Proper name(s)	Common name(s)	Source information
Source ingredient(s)		
4-Aminobenzoic acid, ethyl ester	Benzocaine	Benzocaine