Male Genital Desensitizers

MALE GENITAL DESENSITIZERS 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 - 81 KB) 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 ingredient. 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 August 5, 2019 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 of Administration Topical Dosage Form(s) Acceptable dosage forms for any age category listed in this monograph for the specified route of administration are listed in the Compendium of Monographs Guidance Document. Use(s) or Purpose(s) For reducing oversensitivity in advance of intercourse (US FDA 1992). For temporary male genital desensitisation, helping to slow the onset of ejaculation (US FDA 1992). Helps in temporarily retarding the onset of ejaculation/temporarily slowing the onset of ejaculation/temporarily prolonging the time until ejaculation (US FDA 1992). Helps in the prevention of premature ejaculation (US FDA 1992). The following combined use(s) or purpose(s) is/are also acceptable: For temporary male genital desensitisation to reduce oversensitivity in advance of intercourse and help slow the onset of ejaculation (US FDA 1992). Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) 3 - 7.5% of Benzocaine (US FDA 1992) Note: Should be prepared in a water-soluble base Direction(s) for use Apply a small amount to head and shaft of penis 5-10 minutes before intercourse, or use as directed by a health care practitioner/health care provider/health care professional/doctor/physician (CPhA 1996; US FDA 1992). Wipe off any excess gel before commencing intercourse (CPhA 1996). Use smallest amount possible to achieve desired result. Wash product off after intercourse (CPhA 1996; US FDA 1992). Duration(s) of Use No statement required. Risk Information Caution(s) and warning(s) For external use only. Keep out of reach of children. When using this product, avoid contact with eyes. If contact occurs, rinse thoroughly with water. Premature ejaculation may be due to a condition requiring medical supervision. Stop use and consult a health care practitioner/health care provider/health care professional/doctor/physician if this product, used as directed, does not provide relief (US FDA 1992). Contraindication(s) 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 (HC 2011a,b). Known adverse reaction(s) Stop use if hypersensitivity/allergy occurs (HC 2011a,b; US FDA 1992). 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 All products Store in airtight container protected from light (Martindale 2010). Aerosols/aerosol sprays and pump sprays Store below 40°C (USP DI 2006). Semi-solid preparations (e.g. gels) Store between 15-30°C (USP DI 2006). Solutions Store below 30°C (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. 12 th edition. Washington (DC): Cosmetic, Toiletry and Fragrance Association; 2008. 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Federal Register, Volume 57, Number 119, June 19, 1993. [Accessed 2019 June 13]. Available from: http://cdn.loc.gov/service/ll/fedreg/fr057/fr057119/fr057119.pdf#page=318 USP 35: United States Pharmacopeia and the National Formulary (USP 35 - NF 30). Rockville (MD): The United States Pharmacopeial Convention; 2012. USP DI 2006: Drug Information for the Health Care Professional. 26 th 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. Ash-Bernal R, Wise R, Wright SM. Acquired methemoglobinemia. A retrospective series. Medicine 2004;83(5):265-273. Balicer RD, Kitai E. Methemoglobinemia caused by topical teething preparation: a case report. Scientific World Journal 2004 July 15;4:517-520. Barker SJ, Tremper KK, Hyatt J. 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edition. New York, NY: McGraw-Hill; 2005. Ph.Eur. 2012: European Pharmacopoeia. 7th edition. Strasbourg (FR): Directorate for the Quality of Medicines and HealthCare of the Council of Europe (EDQM), 2012. Public Health Advisory: Benzocaine Sprays marketed under different names, including Hurricaine, Topex, and Cetacaine. [Internet]. [Accessed 2011 June 6]. Available from: http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafety InformationforHeathcareProfessionals/PublicHealthAdvisories/ucm124350.htm Rodriguez LF, Smolik LM, Abehlik AJ. Benzocaine-induced methemoglobinemia: report of a severe reaction and review of the literature. The Annals of Pharmacotherapy 1994;28(5):643- 649. Sachdeva R, Pugeda JG, Casale LR, Meizlish JL, Zarich SW. Benzocaine-induced methemoglobinemia. A potentially fatal complication of transesophageal echocardiography. Texas Heart Institute Journal 2003;30(4):308-310. So T-Y, Farrington E. Topical benzocaine-induced methemoglobinemia in the pediatric population. Journal of Pediatric Health Care 2008;22(6):335-339. Spiller HA, Revolinski DH, Winter ML.Multi-center retrospective evaluation of oral benzocaine exposure in children. Veterinary and Human Toxicology 2000;42(4):228-231. Stoelting RK, Miller RD. Basics of Anesthesia. 4th edition. Publisher: Elsevier Science Health Science Division; 2000. Tantisattamo E, Suwantarat N, Vierra JR, Evans SJ. Atypical presentations of methemoglobinemia from benzocaine spray. Hawai'i Medical Journal 2011;70(6):125-126. Townes PL, Geertsma MA and White MR. Benzocaine-induced methemoglobinemia. American Journal of Diseases of Children 1977;131(6):697-698. Tsigrelis C, Weiner L. Methemoglobinemia revisited: an important complication after transesophageal echocardiography. The European Society of Cardiology 2006;7(6):470-472. Vallurupalli M, Das M, Manchanda S. Infection and the risk of topical anesthetic induced clinically significant methemoglobinemia after transesophageal echocardiography. Echocardiography 2010;27(3):318-323. Vessely MB, Zitsch RP III. Topical anaesthetic-induced methemoglobinemia: A case report and review of literature. Otolaryngology-Head and Neck Surgery 1993:108(6):763-767. VHA Pharmacy Benefits Management Strategic Healthcare Group and the Medical Advisory Panel and the National Center for Patient Safety. A Guidance on the Use of Topical Anesthetics for Naso/Oropharyngeal and Laryngotracheal Procedures; 2006. Wong DH, Wilson SE. Avoiding topical anethesia-induced methemoglobinemia. Obesity Surgery 2005:15(7):1088. Wright R, Lewander W, Woolf A. Methemoglobinemia: etiology, pharmacology, and clinical management. Annals of Emergency Medicine 1999;34(5):646-56. Report a problem on this page Date modified: 2019-03-01

MEDICINAL INGREDIENT(S)

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RISK INFORMATION

Caution(s) and warning(s) For external use only.Keep out of reach of children.When using this product, avoid contact with eyes. If contact occurs, rinse thoroughly with water.Premature ejaculation may be due to a condition requiring medical supervision. Stop use and consult a health care practitioner/health care provider/health care professional/doctor/physician if this product, used as directed, does not provide relief (US FDA 1992). Contraindication(s) 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 (HC 2011a,b). Known adverse reaction(s) Stop use if hypersensitivity/allergy occurs (HC 2011a,b; US FDA 1992).

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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

Route of Administration Topical

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