Health Canada Santé Canada

NATURAL HEALTH PRODUCT

MALE GENITAL DESENSITIZERS

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 the age category listed in this monograph and specified route of administration are indicated 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.

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