

#### NATURAL HEALTH PRODUCT

#### MALE GENITAL DESENSITIZERS

This monograph is intended to serve as a guide to industry for the preparation of ProductLicence 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).

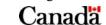
#### **Duration(s) of use**

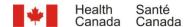
No statement required.

#### **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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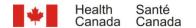
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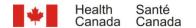
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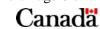
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