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 are synonyms or the statements are synonymous. Either term or statement may be selected by the applicant.

Date January 22, 2013

Proper name(s)

4-aminobenzoic acid ethyl ester (Merck 2012)

Common name(s)

benzocaine (USP 35; Merck 2012; CTFA 2008)

Source material(s)

p-aminobenzoic acid (Merck 2012; CTFA 2008)

Route(s) of administration

topical

Dosage form(s)

Those pharmaceutical dosage forms suited to topical administration. Metered dose and chlorofluorocarbons (CFCs)-based aerosols/aerosol sprays and metered-dose pump sprays are unacceptable dosage forms.
Use(s) or Purpose(s)  Statement(s) to the effect of

- 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).

Dose(s)

Quantity(ies)

3–7.5% in a water-soluble base (US FDA 1992)

Directions for use  Statement(s) to the effect of

- Apply a small amount to head and shaft of penis 5-10 minutes before intercourse, or use as directed by a health care practitioner (CPhA 1996; US FDA 1992).
- Avoid contact with eyes. If this happens, immediately flush thoroughly with water.
- For external use only.
- Keep out of reach of children.
- Use smallest amount possible to achieve desired result.
- Wipe off any excess gel before commencing intercourse (CPhA 1996).

Duration of use

No statement required.

Risk information  Statement(s) to the effect of

Caution(s) and warning(s)

Premature ejaculation may be due to a condition requiring medical supervision. If this product, used as directed, does not provide relief, discontinue use and consult a health care practitioner (US FDA 1992).
Contraindication(s)

If the following symptoms appear: weakness, confusion, headache, difficulty breathing and/or pale, gray or blue coloured skin, stop use and consult a health care practitioner. 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)

Hypersensitivity/allergy has been known to occur; in which case, discontinue use (HC 2011a,b; US FDA 1992).

Non-medicinal ingredients

Must be chosen from the current NHPD Natural Health Products Ingredients Database and must meet the limitations outlined in the database.

Storage conditions

Statement(s) to the effect of

Aerosols/aerosol sprays and pump sprays:
Store below 40°C (USP DI 2006)

All products:
Store in airtight container. Protect from light. (Martindale 2010)

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 NHPD Quality of Natural Health Products Guide.
- The medicinal ingredient must comply with the requirements outlined in the Natural Health Products Ingredients Database (NHPID). In addition, the medicinal ingredient may comply with the specifications outlined in the pharmacopoeial monographs listed in Table 1 below.

Table 1  Benzocaine monographs published in the United States (USP) Pharmacopeia, British (BP) and European (Ph.Eur.) Pharmacopoeias

<table>
<thead>
<tr>
<th>Pharmacopoeia</th>
<th>Monograph</th>
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<tbody>
<tr>
<td>BP</td>
<td>Benzocaine</td>
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<td>Pharmacopoeia</td>
<td>Monograph</td>
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<tr>
<td>Ph. Eur.</td>
<td>Benzocaine</td>
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<td></td>
<td>Benzocaine cream</td>
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<td>Benzocaine gel</td>
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<td></td>
<td>Benzocaine topical solution</td>
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<tr>
<td>USP</td>
<td>Benzocaine topical aerosol</td>
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**References cited**


References reviewed


