# BOY BUTTER DESENSITIZING LUBRICANT- benzocaine cream Boy Butter Lubes

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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# **Drug Facts:**

# **Active Ingredient:**

Benzocaine 7.5%

# Purpose

Male genital desensitizer

## **Indications:**

Helps in the prevention of premature ejaculation.

- For temporary male genital desensitization, helping to slow the onset of ejaculation
- Helps in temporarily slowing the onset of ejaculation
- For reducing oversensitivity in the male in advancer of intercourse.

# Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

# Warnings:

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 physician
- Avoid contact with the eye. If you or your partner develop a rash or irritation, such as burning or itching, discontinue use
- If symptoms persist, consult a physician.

#### Directions:

Apply a small amount to head and shaft of penis before intercourse, or use as directed by a physician

• Wash product off after intercourse

### **Inactive Ingredients:**

Water, Petrolatum, Propylene Glycol, Cyclopentasiloxane, Mineral Oil, Glyceryl Stearate Se, Polysorbate 60, Glycol Distearate, Coconut Oil, Germall 11, Methyparaben, Propylparaben, Yellow 5

### **Questions or Comments:**

For questions or comments, please call 1-818-888-6825

Placeholder Text

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Drug Facts: (Continued)

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Inactive Ingredients: Water Petrolaum,
Propylene (Pyot, Ostpoentasionane, Mineal
Ol, Glyven) Stazata Se, Physiotate 60,
Glyrol Distrasata, Gyvenin, Coronut Ol,
Germall 11, Methylparaben, Propylparaben,
Mallause.

Yellow 5

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# **BOY BUTTER DESENSITIZING LUBRICANT**

benzocaine cream

| Product Information     |                |                    |               |  |
|-------------------------|----------------|--------------------|---------------|--|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:24488-043 |  |
| Route of Administration | TOPICAL        |                    |               |  |

| Active Ingredient/Active Moiety                                     |                   |                       |
|---|-------------------|-----------------------|
| Ingredient Name   | Basis of Strength | Strength              |
| BENZO CAINE (UNII: U3RS Y48 JW5) (BENZO CAINE - UNII: U3RS Y48 JW5) | BENZOCAINE        | 71.9395789 mg in 1 mL |

| Inactive Ingredients     |          |
|--------------------------|----------|
| Ingredient Name          | Strength |
| WATER (UNII: 059QF0KO0R) |          |

| , , ,                                       |  |  |
|---|--|--|
| PETROLATUM (UNII: 4T6 H12BN9 U)             |  |  |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)         |  |  |
| CYCLOMETHICONE 5 (UNII: 0 THT5PCI0 R)       |  |  |
| MINERAL OIL (UNII: T5L8T28FGP)              |  |  |
| GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4) |  |  |
| POLYSORBATE 60 (UNII: CAL22UVI4M)           |  |  |
| GLYCOL DISTEARATE (UNII: 13W7MDN21W)        |  |  |
| GLYCERIN (UNII: PDC6A3C0OX)                 |  |  |
| COCONUT OIL (UNII: Q9L0O73W7L)              |  |  |
| DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)        |  |  |
| METHYLPARABEN (UNII: A2I8 C7HI9 T)          |  |  |
| PROPYLPARABEN (UNII: Z8 IX2SC1OH)           |  |  |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)        |  |  |
|   |  |  |

| P | ackaging         |                          |                      |                           |
|---|------------------|--------------------------|----------------------|---------------------------|
| # | Item Code        | Package Description      | Marketing Start Date | <b>Marketing End Date</b> |
| 1 | NDC:24488-043-83 | 266 mL in 1 BOTTLE, PUMP |                      |                           |

| Marketing Information |  |                      |                    |
|-----------------------|--|----------------------|--------------------|
| Marketing Category    | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final   | part333B                                 | 09/25/2012           |                    |
|                       |  |                      |                    |

# Labeler - Boy Butter Lubes (961956229)

# **Registrant -** Creation's Garden Natural Products (961956229)

| Establishment                      |         |           |                            |  |
|------------------------------------|---------|-----------|----------------------------|--|
| Name                               | Address | ID/FEI    | <b>Business Operations</b> |  |
| Creation's Garden Natural Products |         | 961956229 | manufacture(24488-043)     |  |

Revised: 9/2012 Boy Butter Lubes