

## **BOY BUTTER EXTREME H2O 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 Ingredients:**

Benzocaine 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 advance 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 eyes. 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 off product after intercourse.

#### **Inactive Ingredients:**

Water, Cyclopentasiloxane, Propylene Glycol, Glyceryl Stearate and PEG-100 Stearate, Paraffinum Liquidum (Mineral Oil), Butyrospermum Parkii (Shea Butter), Tricaprylin, Cocos Nucifera (Coconut Oil), Glycerin, Triethanolamine, Carbomer, Aloe Barbadosensis Leaf Juice, Tocopheryl (Vitamin E) Acetate, Methylparaben, Diazolidyl Urea, Propylparaben Yellow 5, Fragrance.

#### **Questions or Comments:**

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

Placeholder Text



Drug Facts:	
<b>Active Ingredient:</b> Benzocaine 5%	<b>Purpose:</b> Male genital desensitizer
<b>Indications:</b> 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 advance of intercourse.	
3 oz. Extreme H2O ▶	

Drug Facts: (Continued)	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Warnings:</b> 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 eyes. If you or your partner develops a rash or irritation, such as burning or itching, discontinue use ■ If symptoms persist, consult a physician.	
<b>Directions:</b> Apply a small amount to	

Drug Facts: (Continued)	
head and shaft of penis before intercourse, or use as directed by a physician. ■ Wash product off after intercourse.	
<b>Inactive Ingredients:</b> Water, Cyclopentasiloxane, Polyurethane Glycol, Glycerol Stearate and PEG-100 Stearate, Paraffinum Liquidum (Mineral Oil), Butyrospermum Partitum (Shea Butter), Tricaprylin, Cocos Nucifera (Coconut Oil), Glycerin, Tetrahydrocannabinol, Carbomer, Aloe Barbadensis Leaf Juice, Tocopherol (Vitamin E) Acetate, Methylparaben, Diandryl Urea, Propylparaben, Willow Bark Extract, Fragrance.	
<b>Questions or Comments:</b> For questions or comments please call 1-818-888-6825	

## BOY BUTTER EXTREME H2O DESENSITIZING LUBRICANT

benzocaine cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:24488-003
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	4.25 g in 85.05 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CYCLOMETHICONE 5 (UNII: 0TH5PC10R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
MINERAL OIL (UNII: T5L8T28FGP)	
SHEA BUTTER (UNII: K49155WL9Y)	
TRICAPRYLIN (UNII: 6P92858988)	
COCONUT OIL (UNII: Q9L0O73W7L)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
VANILLA (UNII: Q74T35078H)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24488-003-45	85.05 g in 1 CONTAINER		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	06/27/2011	

**Labeler** - Boy Butter Lubes (961956229)**Registrant** - Creations Garden Natural Products (961956229)**Establishment**

Name	Address	ID/FEI	Business Operations
Creations Garden Natural Products		961956229	manufacture

Revised: 6/2011

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