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.

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

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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

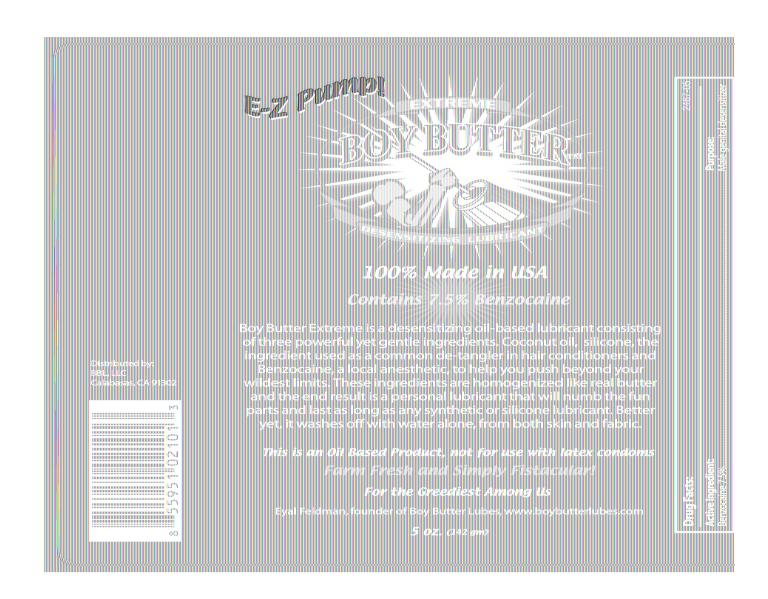
Inactive Ingredients:

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



BOY BUTTER DESENSITIZING LUBRICANT

benzocaine cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24488-003
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	10.65 g in 142 g	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

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CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
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: Z8IX2SC1OH)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:24488-003-05	142 g in 1 BOTTLE, PUMP		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	05/23/2011	

Labeler - Boy Butter Lubes (961956229)

Registrant - Creation's Garden Natural Products (961956229)

Establishment			
Name	Address	ID/FEI	Business Operations
Creation's Garden Natural Products		961956229	manufacture

Revised: 5/2011 Boy Butter Lubes