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

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:

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Questions or Comments:

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

Placeholder Text

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Drug Facts: (Continued)
Keep out of reach of children.





BOY BUTTER DESENSITIZING LUBRICANT

benzocaine cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24488-042
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	73.9395789 mg in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
CYCLOMETHICONE 5 (UNII: 0 THT5PCI0 R)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)		
MINERAL O IL (UNII: T5L8T28FGP)		
SHEA BUTTER (UNII: K49 155WL9 Y)		
TRICAPRYLIN (UNII: 6P92858988)		
COCONUT OIL (UNII: Q9L0O73W7L)		
GLYCERIN (UNII: PDC6A3C0OX)		

TROLAMINE (UNII: 903K93S3TK)		
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)		
METHYLPARABEN (UNII: A218 C7HI9 T)		
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)		

ı	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:24488-042-82	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	Business Operations	
Creation's Garden Natural Products		961956229	manufacture(24488-042)	

Revised: 9/2012 Boy Butter Lubes