PROLONG- benzocaine gel Product Max Group Inc

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.

PROLONG - 089

Drug Facts Active Ingredient

Benzocaine 5%

Purpose

Male Genital Desensitizer

Keep out of reach of children

Keep out of reach of children.

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

Uses

• Helps in the prevention of premature ejaculation.

Warnings

For external use only.

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

Directions

- Apply a small amount to head and shaft of penis before intercourse.
- Wash product off after intercourse.

Other Information

Do not use if safety seal under cap is broken or missing.

Inactive Ingredients

Hydroxyethylcellulose, Methylparaben, PEG-8, Propylene Glycol, Propylparaben, Water

PROLONG product label

www.bodyactionproducts.com

Distributed by:

Body Action Products

Lutz, FL 33559

ACTION BODY PRODUCTS

Benzocaine Male Genital Desensitizer

PROLONG

FOR MEN

Helps Prolong Sexual Pleasure

Lubricating Gel

2 FL OZ (60 ml)



PROLONG

benzocaine gel

Product Information	Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70742-089		
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	2833 mg in 60 mL

Inactive Ingredients			
Ingredient Name	Strength		
HYDROXYETHYL CELLULOSE (140 MPA.S AT 5%) (UNII: 8136Y38GY5)			
METHYLPARABEN (UNII: A2I8 C7HI9 T)			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			
WATER (UNII: 059QF0KO0R)			

	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:70742-089-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/15/2016		
П					

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part348	06/15/2016		

Labeler - Product Max Group Inc (134893911)

Registrant - Product Max Group Inc (134893911)

Revised: 8/2016 Product Max Group Inc