PLEASURE BALM KAMA SUTRA- benzocaine gel Kama Sutra

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.

Pleasure Balm

Active Ingredients Purpose

Benzocaine 5.0 % Male genital desensitizer

Use

Helps in temporarily prolonging time until ejaculation

Keep out of reach of children. If swallowed, seek medical assistance or contact a Poison Control Center immediately.

Discontinue use and consult a doctor if

This product, used as directed does not provide relief

You or your partner develops a rash or irritation, such as burning or itching

Condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days

The following symptoms appear: weakness, confusion, headache, difficulty breathing and/or pale, gray or blue colored skin as these may be signs of methemoglobinemia

Warnings

For external use only

Do not use if allergic to Benzocaine or any other ingredient in this product

Safe to use only with latex condoms only

Premature ejaculation may be due to condition requiring medical supervision

Consult a doctor prior to use if partner is pregnant

Avoid contact with eyes: if this happens, rinse thoroughly with water

Known adverse reactions Hypersensitivity/allergy has been known to occur, in such a case, discontinue use.

Directions

Adults, 18 and over. Apply a small amount to head and shaft of penis 5-10 minutes before intercourse, or use as directed by a health care practitioner. Use the smallest amount to achieve the desired result. Wipe off any excess gel before intercourse. Wash product off after intercourse.

Inactive Inagredients: Blue 1 (CI 42090), Disodium EDTA, Hydroxyethylcellulose, Mentha Piperita (peppermint oil), PEG-8, Polysorbate 60, Propylene Glycol, Sodium Saccharin, Water (Aqua/Eau), Yellow 5 (CI 19140), Yellow 6 (CI 15985)





Kama Sutra

Pleasure Balm

Prolonging Gel for Men

Male Genital Desensitizer

Gel pour Prolonger pour hommes

Genitaux Masculin Desensibilisateur

1.7 fl oz 50 ml

PLEASURE BALM KAMA SUTRA								
benzocaine gel								
Product Information								
Product T ype	HUMAN OTC DRUG	Item Code (Source)		NDC:75956-147				
Route of Administration	TOPICAL							
Active Ingredient/Active Moiety								
Ingr	Basis of Stre	ngth	Strength					
BENZOCAINE (UNII: U3RSY48JW5) (B	BENZOCAINE		5 g in 100 mL					

Inactive Ingredients									
Ingredient Name						Strength			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)									
EDET	EDETATE DISO DIUM (UNII: 7FLD9 1C86K)								
CETYL HYDROXYETHYLCELLULOSE (350000 MW) (UNII: T7SWE4S2TT)									
MEN	THA PIPERITA (UN	III: 79 M2M2UDA9)							
POL	YETHYLENE GLYC	COL 400 (UNII: B697894SGQ)							
POL	POLYSORBATE 60 (UNII: CAL22UVI4M)								
PRO	PYLENE GLYCOL	(UNII: 6DC9Q167V3)							
SACCHARIN SO DIUM (UNII: SB8ZUX40TY)									
WATER (UNII: 059QF0KO0R)									
FD&	CYELLOWNO.5	(UNII: I753WB2F1M)							
FD&C YELLOW NO.6 (UNII: H77VEI93A8)									
Pac	kaging								
#	Item Code	Package Description	Marketin	Marketing Start Date		Marketing End Date			
1 ND	C:75956-147-01	50 mL in 1 TUBE							
Ma	rketing Info	rmation							
	keting Category	Application Number or Monograph Citation		Marketing Start Date		Marketing End Date			
1vidi	Realing Categoly	Application fumber of Monog		Markeung Start		incluig Linu Date			
OTC	monograph final	part348		09/12/2013					

Labeler - Kama Sutra (053877858)

Registrant - Kama Sutra (053877858)

Establishment									
Name	Address	ID/FEI	Business Operations						
Cosmetic Enterprise		0 1770 1475	manufacture(75956-147)						

Revised: 1/2015

Kama Sutra