EJECTDELAY GEL- benzocaine gel
Innovus Pharmaceuticals, 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.

Drug Facts

Active Ingredients

Benzocaine 7.5%

Purpose

Male genital desensitizer

Indications

Helps in the prevention of premature ejaculation

Warnings

For external use only

When using this product

Avoid contact with eyes

Stop use and ask a doctor if

- Premature ejaculation may be due to a condition requiring medical supervision
- This product, used as directed, does not provide relief, discontinue use and consult a physician
- You or your partner develop a rash or irritation, such as burning or itching, discontinue use
- If symptoms persist, consult a doctor

Keep out of reach of children

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

Directions

Apply a small amount to head and shaft of penis before intercourse, or use as directed by a physician.

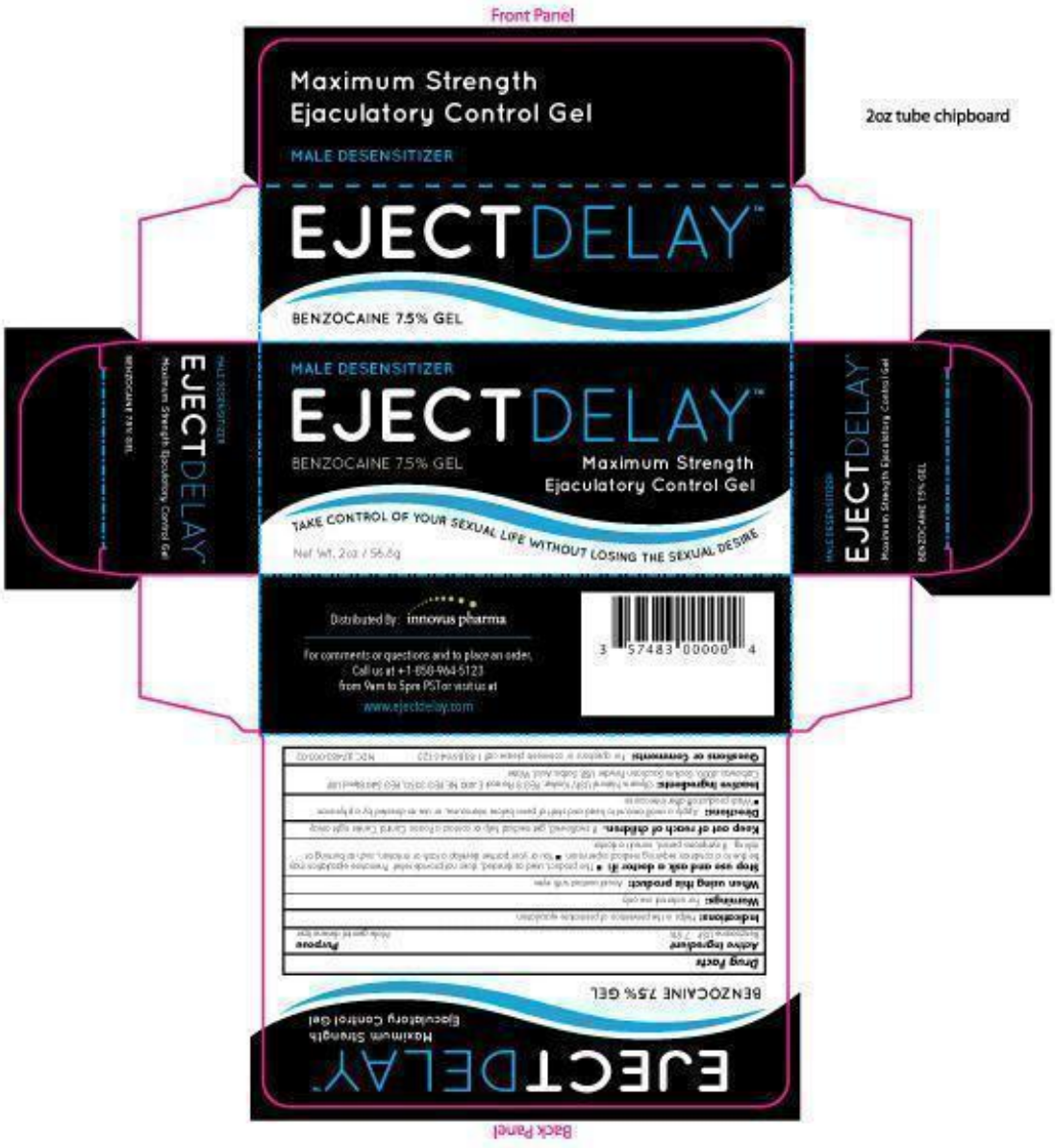
Wash product off after intercourse

Inactive Ingredients

Glycerin Natural USP Kosher, PEG 8 Pluracol E 400 NF, PEG 3350, PEG 540 Blend USP, Carbowax 4000, Sodium Saccharin Powder USP, Sorbic Acid, Water

Questions or Comments

For questions or comments please call 1-858-964-5123



EJECTDELAY GEL

benzocaine 7.5% gel

Product Information			
Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:57483-003
Route of Administration	TOPICAL	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Benzocaine (Benzocaine)	Benzocaine	7.5 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**

Glycerin	
POLYETHYLENE GLYCOL 400	
POLYETHYLENE GLYCOL 3350	
POLYETHYLENE GLYCOL 4000	
SACCHARIN SODIUM	
SORBIC ACID	
Water	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57483-003-02	1 in 1 BOX		
1	NDC:57483-003-03	56.8 g in 1 TUBE		
2	NDC:57483-003-06	5 g in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	07/15/2013	

Labeler - Innovus Pharmaceuticals, Inc. (962507187)

Registrant - Innovus Pharmaceuticals, Inc. (962507187)

Establishment

Name	Address	ID/FEI	Business Operations
U.S. Pharmaceuticals, Inc.		009248480	manufacture(57483-003)

Revised: 11/2013 Innovus Pharmaceuticals, Inc.