

PROLONG PLUS- benzocaine cream
WSM Investment LL. Topco Sales

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.

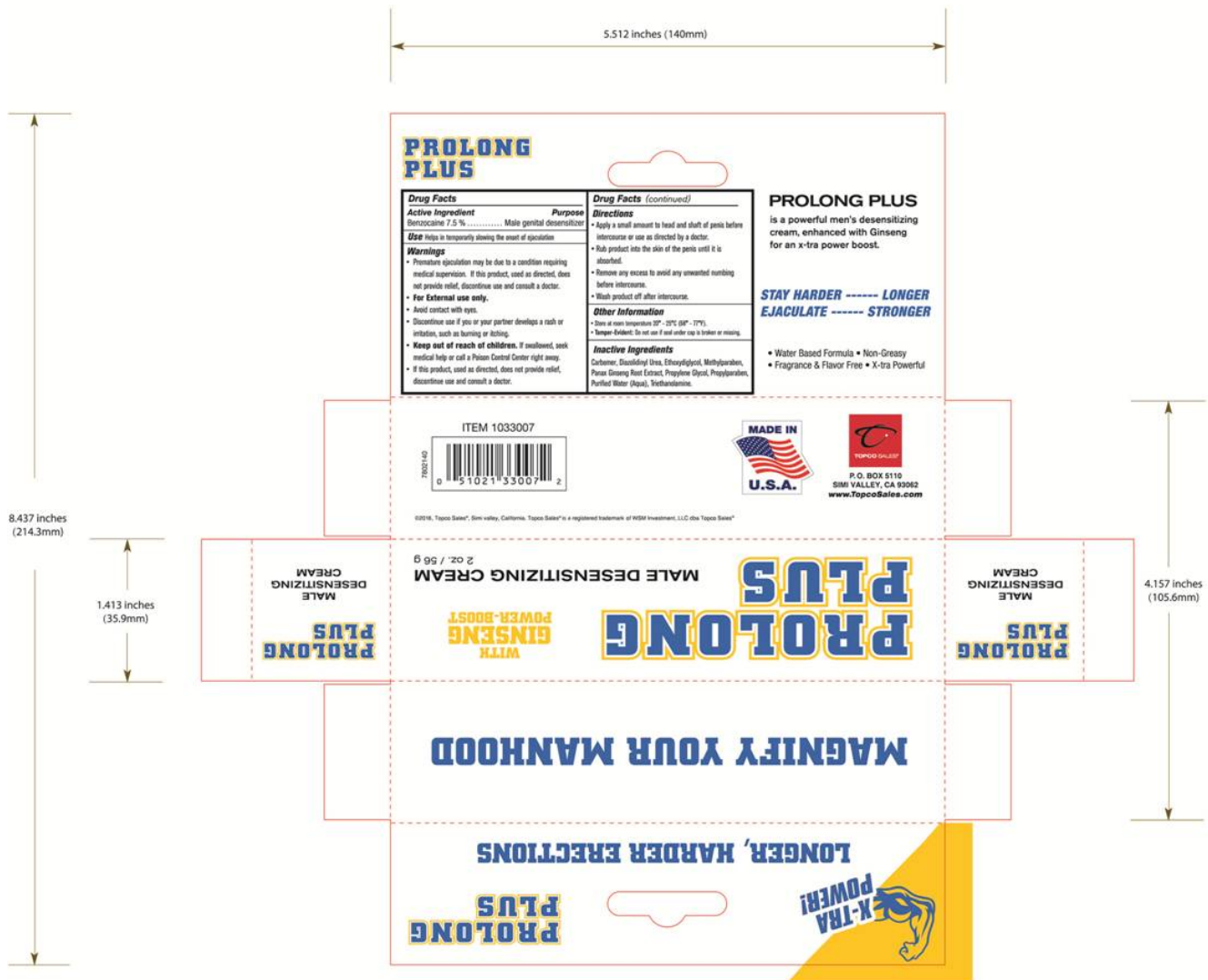
Benzocaine - 7.5%

Male Genital Desensitizer

Helps in temporarily slowing the onset of ejaculation.

- 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.
- **For external use only.**
- Avoid contact with eyes.
- Discontinue use if you or your partner develops rash or irritation, such as burning or itching.
- **Keep out of reach of children.** If swallowed, seek medical help or call a Poison Control Center right away.
- If this product, used as directed, does not provide relief, discontinue use and consult a doctor.
- Apply a small amount to head and shaft of penis before intercourse or use as directed by a doctor.
- Rub product into the skin of the penis until it is absorbed.
- Remove any excess to avoid any unwanted numbing before intercourse.
- Wash product off after intercourse.
- Store at room temperature 20°-25°C (68°-77°F).
- **Tamper-Evident:** Do not use if seal under cap is broken or missing.

Carbomer, Diazolidinyl Urea, Ethoxydiglycol, Methylparaben, Panax Ginseng Root Extract, Propylene Glycol, Propylparaben, Purified Water (Aqua), Triethanolamine.



PROLONG PLUS

benzocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69797-104
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RS Y48JW5) (BENZOCAINE - UNII:U3RS Y48JW5)	BENZOCAINE	4.2 g in 56 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
AMERICAN GINSENG (UNII: 8W75VCV53Q)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	

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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69797-104-01	56 g in 1 TUBE; Type 0: Not a Combination Product	12/19/2017	

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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part348	12/19/2017	

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Labeler - WSM Investment LL. Topco Sales (040346439)

Establishment

Name	Address	ID/FEI	Business Operations
WSM Investment LLC. Topco Sales		040346439	manufacture(69797-104)

Revised: 12/2017

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