PREBOOST- benzocaine liquid 944 Corp

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.

Male Genital Desensitizer Towelette

Drug Facts

Active Ingredients

Benzocaine USP 4.0%

Purpose

Male Genital Desensitizer

Use

Helps in temporarily prolonging time until ejaculation.

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 doctor.

- Avoid contact with the eyes.
- If 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 doctor. Wash product off after intercourse.

Inactives

purified water, Ethyl Alcohol (SDA 40B), Propylene Glycol

PRINCIPAL DISPLAY PANEL - pouch label

PREBOOSTTM

MALE DESENSITIZING WIPES

Helps in temporarily prolonging time until ejaculation

Developed by Dr. Harry Fisch www.preboost.com

Manufactured for 944 Corp 944 Park Ave, New York, NY 10028 www.preboost.com

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1 single-use premoistened towelette

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PRINCIPAL DISPLAY PANEL - box label

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MALE DESENSITIZING WIPES

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10 single-use premoistened towelette

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PREBOOST

benzocaine liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:62192-8500

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthbenzocaine (UNII: U3RSY48JW5) (benzocaine - UNII:U3RSY48JW5)benzocaine4 g in 100 mL

Inactive Ingredients

Ingredient Name
Strength

alcohol (UNII: 3K9958V90M)

water (UNII: 059QF0KO0R)

propylene glycol (UNII: 6DC9Q167V3)

Packaging # Item Code Package Description Marketing Start Date Marketing End Date 1 NDC:62192-8500-1 10 in 1 BOX 1 1.2 mL in 1 PACKET

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part348	02/18/2014	

Labeler - 944 Corp (054365072)

Registrant - Safetec of America, Inc. (874965262)

Establishment					
Name	Address	ID/FEI	Business Operations		
Safetec of America, Inc.		874965262	MANUFACTURE(62192-8500)		

Revised: 2/2014 944 Corp