

OPTIMUM ROCK HARD CREAM- cream desensitizer cream
Private Label Productions LLC

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.

Cal EX Desensetizer Cream 59 mL

Active Ingredient(s)

Benzocaine.....7.5%

Purpose

Male Genital Desensitizer

Use

Helps in prevention of premature ejaculation

Warnings

Methemoglobinemia warning: Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have use this product before. Stop use and seek immediate medical attention if you or a child in your care develops: † pale, gray, or blue colored skin (cyanosis) * headache e rapid heart rate † shortness of breath e dizziness or lightheadedness e fatigue or lack of energy

Allergy alert: Do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or any other 'caine' anesthetics.

For external use only. Avoid contact with eyes. If you or your partner develop a rash or irritation such as burning or itching discontinue use. Premature ejaculation may be due to a condition requiring medical supervision. Keep out of reach of children. If symptoms persist consult a physician. If this product, used as directed, does not provide relief, discontinue use and consult a doctor.

Do Not Use ‹ For teething @ In children under 2 years of age

Keep out of reach of children.

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. Children under 2 years of age: Do not use.

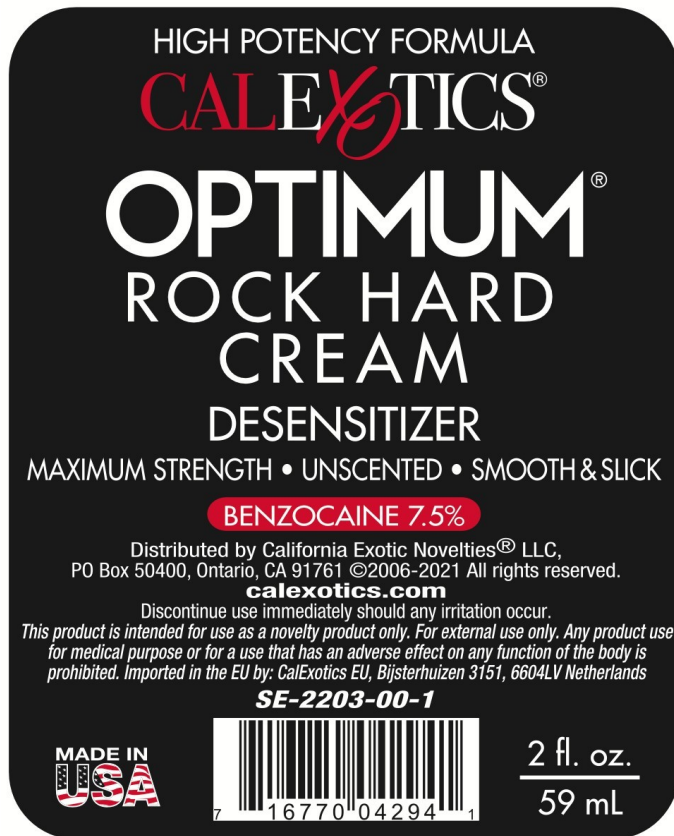
Other information

Store at 20-25°C (equals 68-77°F)

Inactive ingredients

Acrylates/C 10-30 Alkyl Acrylate Crosspolymer, Diazolidinyl Urea, Ethoxydiglycol, Methylparaben, Propanediol, Propylene Glycol, Propylparaben, Triethanolamine, Water (Aqua)

Package Label - Principal Display Panel



59 mL NDC: 77632-126-01

Drug Facts	
Active Ingredient	Purpose
Benzocaine.....7.50% w/v	Male Genital Desensitizer
Uses Helps in prevention of premature ejaculation	
Warnings	
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OPTIMUM ROCK HARD CREAM

cream desensitizer cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77632-126
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	7.5 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPANEDIOL (UNII: 5965N8W85T)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77632-126-01	59 mL in 1 TUBE; Type 0: Not a Combination Product	05/31/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/31/2023	

Labeler - Private Label Productions LLC (046278265)

Revised: 7/2023

Private Label Productions LLC