PREMJACT MALE DESENSITIZER POUND INTERNATIONAL- lidocaine spray, metered Pound International

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.

Premjact Male Genital Desensitizer Spray

Active Ingredient

Purpose

Lidocaine Base USP 9.6% w/w (approximately 10 mg per spray) Topical Analgesic

Use temporarily reduces sensitivity of the penis, which helps to delay ejaculation in cases of overrapid or premature ejaculation (coming to a climax too quickly

Keep out of reach of children

Stop use and consult a doctor

- if you or your partner develop a rash or irritation, such as burning or itching
- If you do feel unwell or have any unpleasant effects after using the spray
- if this product, used as directed, does not provide relief. Premature ejaculation may be due to a condition requiring medical supervision.

Warnings

For external use only

Allergy alert: do not use this product if you or your partner are allergic (sensitive) to local anesthetics

Do not use

- on broken or inflamed skin
- if your partner is pregnant

Ask a doctor before use if you have, or ever had, liver or kidney problems

Ask a doctor or pharmacist before use if you are already taking prescribed drugs

When using this product

- do not get into eyes
- do not inhale
- do not exceed a maximum of 24 sprays in 24 hours

directions

- Apply 3 or more sprays, not to exceed 10, to the head and shaft of the penis before intercourse or use as directed by a doctor
- Wash product off after intercourse
- correct quantity and time of application will be determined by individual requirements and you should always use the minimum effective quantity

There are no inactive ingredients



Premjact

Male Genital Desensitizer Spray 7/16 Fl.Oz.

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lidocaine spray, metered

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57707-058
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
LIDO CAINE (UNII: 98 PI200987) (LIDO CAINE - UNII: 98 PI200987)	LIDOCAINE	9.6 g in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
ISOPROPYL MYRISTATE (UNII: 0 RE8K4LNJS)			
STEARIC ACID (UNII: 4ELV7Z65AP)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57707-058-02	1 in 1 CARTON	05/09/2013	
1	NDC:57707-058-01	12 mL in 1 CAN; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/09/2013	

Labeler - Pound International (802685065)

Establishment				
Name	Address	ID/FEI	Business Operations	
FLEET LABORATORIES LTD		217269489	manufacture(57707-058)	

Revised: 1/2019 Pound International