PREMJACT MALE DESENSITIZER POUND INTERNATIONAL- lidocaine spray, metered FLEET LABORATORIES LTD

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 FLOz.

PREMJACT MALE DESENSITIZER POUND INTERNATIONAL lidocaine spray, metered **Product Information** HUMAN OTC DRUG NDC:70233-004 **Product Type** Item Code (Source) TOPICAL **Route of Administration Active Ingredient/Active Moiety Ingredient** Name **Basis of Strength** Strength LIDO CAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987) LIDOCAINE 9.6 g in 100 mL

Inactive Ingredients							
	Strength						
ISOP							
STEA							
Packaging							
#	Item Code	Package Description		Marketing Start Date	Marketing End Date		
				5/09/2013			
1 ND	DC:70233-004-02	1 in 1 CARTON	Ĺ	15/09/2013			
		1 in 1 CARTON 12 mL in 1 CAN; Type 0: Not a Combination Produ		55/09/2013			
				15/09/2013			
				15/09/2013			
1 ND		12 mL in 1 CAN; Type 0: Not a Combination Produ		15/09/2013			
1 ND	DC:70233-004-01	12 mL in 1 CAN; Type 0: Not a Combination Produ	zt	Marketing Start Date	Marketing End Date		

Labeler - FLEET LABORATORIES LTD (217269489)

Registrant - FLEET LABORATORIES LTD (217269489)

Establishment

Name	Address	ID/FEI	Business Operations
FLEET LABORATORIES LTD		217269489	manufacture(70233-004)

Revised: 1/2017

FLEET LABORATORIES LTD