

STAG 9000 DELAYSPRAY FOR MEN- lidocaine spray
LOTUSA 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.

STAG 9000 DELAY SPRAY FOR MEN

- a. Lidocaine 10.0% w/v (Approximately 10 mg per spray)
- b. Caprylic/ Capric Triglyceride,
- c. Ethanol,
- d. Isopropyl myristate,
- e. Tocopherol

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Lidocaine 10.0% w/v (Approximately 10 mg per spray) Purpose: Male genital desensitizer

Purpose

Male genital desensitizer

Use

- helps in the prevention of premature ejaculation
- helps in temporarily prolonging the time until ejaculation
- for reducing oversensitivity in the male in advance of intercourse

Warnings

For external use only. Avoid contact with the eyes.

Do not use

- on broken or inflamed skin

When using this product do not get into eyes. In case of contact, rinse eyes thoroughly with water. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

If you or your partner develop a rash or irritation, such as burning or itching, discontinue use. If symptoms persist, consult a doctor. Ask a doctor before use.

If your partner is pregnant or breast-feeding

If you have or have had liver or kidney problems. When using this product

do not get into eyes or nostrils

do not inhale

do not exceed a maximum of 6 sprays in 24 hours.

Always use the minimum amount effective for you

Allow 5-15 minutes to dry prior to intercourse. 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. This product is not compatible with condoms.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Use only as directed.
- Apply 1-2 sprays, not to exceed 6, to the head and shaft of the penis before intercourse, per use as directed by a doctor.
- Wash product off after intercourse. Please read the instructions for use and advise use carefully to achieve best results.

Other information

- Store at room temperature 20-25 °C (68-77 °F)

Inactive ingredients

Caprylic/ Capric Triglyceride, Ethanol, Isopropyl myristate, Tocopherol

Package Label - Principal Display Panel

20 mL NDC: 80554-004-02



STAG 9000 DELAYSPRAY FOR MEN

lidocaine spray

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:80554-004

Route of Administration		TOPICAL		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)		LIDOCAINE	10 g in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)				
TOCOPHEROL (UNII: R0ZB2556P8)				
ALCOHOL (UNII: 3K9958V90M)				
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80554-004-01	20 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	09/01/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final		part348	03/30/2020	

Labeler - LOTUSA LLC. (122415153)

Registrant - LOTUSA LLC. (122415153)

Establishment			
Name	Address	ID/FEI	Business Operations
FRENCH MALIHOME PERSONAL PRODUCTS LIMITED		664283791	manufacture(80554-004)