# 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.

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#### STAG 9000 DELAY SPRAY FOR MEN

- a. Lidocaine 10.0% w/v (Approximately10 mgper spray)
- b. Caprylic/Capric Triglyceride,
- c. Ethanol,
- d. Isopropyl mrystate,
- 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 (Approximately10 mgper spray) Purpose: Male genital desensitizer

#### **Purpose**

Male genital desensitizer

#### Use

- helps in the preventation of premature ejaculation
- helps in temporarily prolonging thetime until ejaculation
- for reducing oversensitivity in the male inadvance 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 withwater. 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

Allow5-15 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.
- Apply1-2 sprays, not to exceed 6, to the head and shaft of the penis before intercourse, peruse as directed by a doctor
- Wash product off after intercourse Please read the instructions for use and advice use carefully to achievebest results

#### Other information

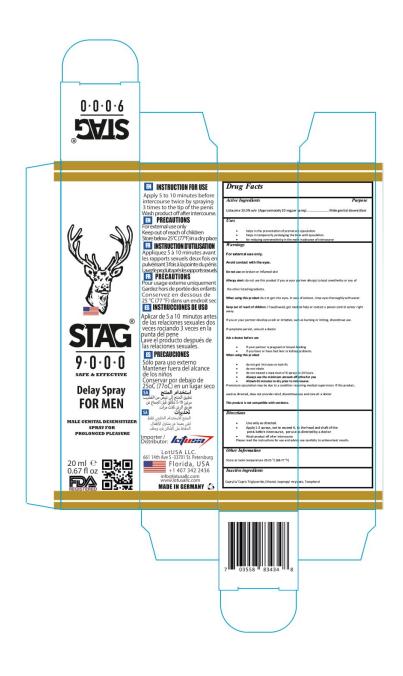
• Store atroom temperature 20-25 o C (68-77 o F)

### **Inactive ingredients**

Caprylic/ Capric Triglyceride, Ethanol, Isopropyl mrystate, Tocopherol

## **Package Label - Principal Display Panel**

20 mL NDC: 80554-004-02



## STAG 9000 DELAYSPRAY FOR MEN

lidocaine spray

Product Information
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:80554-004

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TOPICAL

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Ingredient Name	Basis of Strength	Strength	
LIDO CAINE (LINII: 98 PI200 987) (LIDO CAINE - LINII: 98 PI200 987)	LIDOCAINE	10 g in 100 mI.	

mactive ingredients				
Ingredient Name	Strength			
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)				
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	<b>Business Operations</b>	
FRENCH MALIHOME PERSONAL PRODUCTS LIMITED		664283791	manufacture(80554-004)	

LOTUSA LLC. Revised: 9/2020