## STAMA PRO- lidocaine spray Cerno Pharmaceuticals

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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#### ACTIVE INGREDIENT

#### **Each milliliter contains**

Active Ingredient	Purpose
Lidocaine Hydrochloride	Male Genital
9.6%	Desensitizer

#### **INACTIVE INGREDIENT**

Methylparaben, Propylparaben, Carboxymethyl Cellulose Sodium, Deionized Water.

#### KEEP OUT OF REACH OF CHILDREN

If swallowed, get medical help or contact a Poison Control Center.

#### **INDICATIONS & USAGE**

Helps in the prevention of premature ejaculation.

#### WARNINGS

For external use only. ■ Avoid contact with the eyes.

#### Stop use and ask a doctor:

- If you or your partner develop a rash or irritation such as burning or itching. If symptoms persist, consult a doctor.
- 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.

#### **DOSAGE & ADMINISTRATION**

Remove the protective cap. Press the actuator down repeatedly until product dispenses to prime spray pump.

Apply 3 or more sprays, not to exceed 10, to head and shaft of penis 8 minutes before intercourse, or use as directed by a

doctor. Wash product off after intercourse. After spraying, place the cap back on.

#### **PURPOSE**

Male Genital Desensitizer

#### Other Information

■ Keep away from fire and flames. ■ Store at 20-25°C (68-77°F) Made in the U.S.A.



# STAMA PRO lidocaine spray Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:70107-302

Route	οf	Λd	min	ictra	tion
ROHE		$A_{II}$			

TOPICAL

<b>Active Ingredient/Active Moiety</b>	nt/Active Moiety	Ingredie	Active
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I	Ingredient Name	Basis of Strength	Strength
I	LIDO CAINE (UNII: 98PI200987) (LIDO CAINE - UNII:98PI200987)	LIDOCAINE	96 mg in 1 mL

Inactive	Ingredients

inactive ingredients				
Ingredient Name	Strength			
METHYLPARABEN (UNII: A2I8C7HI9T)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)				
WATER (UNII: 059QF0KO0R)				

#### **Packaging**

# Item Code Package Description		Marketing Start Date	Marketing End Date
1 NDC:70107-302-	13.5 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	0 1/11/20 17	

### **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part348	0 1/11/20 17			

## Labeler - Cerno Pharmaceuticals (079821037)

Establishment			
Name	Address	ID/FEI	Business Operations
Cerno Pharmaceuticals		079821037	MANUFACTURE(70107-302)

Revised: 1/2017 Cerno Pharmaceuticals