

**TRIMO SAN- oxyquinoline sulfate and sodium lauryl sulfate jelly  
CooperSurgical, Inc.**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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**Trimo San**

**Manufactured for:**

**CooperSurgical Company**

**95 Corporate Drive**

**Trumbull, CT 06611**

**Toll Free: (800) 243-2974**

**Fax: (800) 262-0105**

**www.coopersurgical.com**

**TRIMO-SAN – REF MX5030**

**For Pessary Wearers - A Vaginal Product**

**Rx Only**

**PLEASE READ CAREFULLY**

A pessary is considered a foreign body in the vagina. For long-term pessary users, it is important to maintain the normal acidic pH of the vagina. **TRIMO-SAN**, a deodorant vaginal gel, may help pessary wearers restore and maintain a normal acidic pH of the vagina.

**CONTENTS:**

Hydroxyquinoline Sulfate 0.025%; Sodium Lauryl Sulfate N.F. 0.01%. Adjusted with Triethanolamine to pH 4 in water dispersible base composed of Glycerine, Carbomer N.F., Citric Acid, Sodium Citrate U.S.P., Methylparaben N.F., Perfume and Antifoam Emulsion N.F.

**STORAGE:**

**AFTER EACH USE** Wipe threads of tube and the inside of the cap. **RE-CAP TIGHTLY.** Store at room temperature.

**PURPOSE OF TRIMO-SAN**

1. To help restore and maintain normal vaginal acidity.
2. To coat walls of vagina with a lubricating film that may help reduce odor-causing bacteria, since bacteria can flourish in abnormal vaginal pH.

**INFORMATION ABOUT TRIMO-SAN**

1. **TRIMO-SAN** Gel will not stain skin or natural fabrics.
2. **TRIMO-SAN** Gel helps eliminate odors, which may be associated with wearing a pessary.
3. Dosage of **TRIMO-SAN** Gel may be adjusted from one-half an applicator to a full applicator to

obtain the desired results without messy leakage.

## **WARNING:**

Chemicals in various preparations can interact with the pessary material resulting in discoloration or deterioration of the pessary.

**TRIMO-SAN** does not have a deleterious effect on any Milex pessary. Testing should be performed before using any other vaginal preparation with a pessary unless specifically prescribed by your healthcare professional.

## **TRIMO-SAN and PREGNANCY**

**TRIMO-SAN** has **NOT** been tested for use during pregnancy.

- CooperSurgical does not recommend the use of **TRIMO-SAN** during pregnancy.
- If you wish to become pregnant, do not use **TRIMO-SAN** or any other personal hygiene product vaginally (douches, vaginal sprays, jellies or suppositories), for 6 hours prior to or following intercourse. Any product used within this time period could interfere with conception.

## **GENERAL INFORMATION**

- New pessary wearers should use a ½ applicator of **TRIMO-SAN** 3 times the first week after original insertion of pessary.
- Use **TRIMO-SAN** ½ applicator twice a week thereafter unless otherwise directed by your healthcare professional.
- Reaction or irritation caused by **TRIMO-SAN** is very rare, but should it occur, discontinue use.
- If symptoms persist or worsen, contact your healthcare professional

THIS PRODUCT IS INTENDED FOR MULTIPLE USE BY **ONE PATIENT ONLY**.

## **PROPER USE OF MILEX JEL-JECTOR**

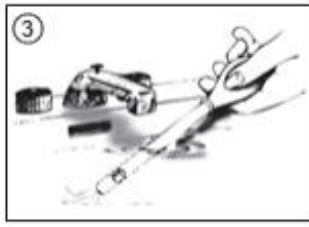
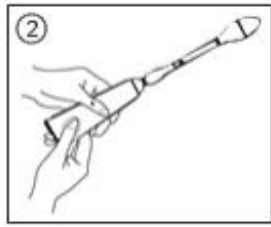
1. Unscrew cap from tube
2. Pierce end of tube with top of cap (a small amount of **TRIMO-SAN** may escape when top of tube is pierced).
3. Attach threaded end of Milex Jel-Jector to **TRIMO-SAN** tube (see □).
4. While holding tube with attached Milex Jel-Jector (see □), squeeze tube from bottom until **TRIMO-SAN** reaches specified dosage level.
5. Detach Milex Jel-Jector from tube. Gently insert Jel-Jector approximately ½ inch into the vagina. Squeeze bulb vigorously once to dispense gel. Keep bulb compressed until the Milex Jel-Jector is removed from the vagina.

NOTE: For those wearing an Inflat-o-ball or Cube Pessary, remove pessary per physician's instruction before application of **TRIMO-SAN**.

6. Clean Milex Jel-Jector immediately after use by flushing Jector (compressing bulb) several times, holding Jel-Jector under water (see □).

NOTE: The "pin" hole at the top of the bulb is an air release hole. Do **NOT** tape over this hole or otherwise block this hole. This "pin" hole is not a defect in the bulb.

7. After each use, wipe threads of tube and inside of cap. Recap tightly.



**IMPORTANT IF YOU HAVE ANY OF THE FOLLOWING SIGNS OR SYMPTOMS,  
CONSULT A HEALTHCARE PROFESSIONAL**

- A. A discharge, which is unusual in color, consistency or amount.
- B. A burning or itching sensation in the vaginal area.
- C. A foul odor associated with vaginal discharge.
- D. Any of the above especially if accompanied by unusual swelling or tenderness, fever, pains or cramps in the lower abdomen.

**NOTE**

If this product is being used with a pessary, follow your healthcare professional's instructions explicitly. Consult your health care professional for all other medically-related advice.

**PRINCIPAL DISPLAY PANEL**

NDC 59365-5030-0

TRIMO-SAN

VAGINAL JELLY SET

with Nylon Milex Jel-Jector

CONTENTS: 1 ea. 4 oz tube (113.4 grams) and applicator

Rx Only



Revised: 4/2018

## TRIMO SAN

oxyquinoline sulfate and sodium lauryl sulfate jelly

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:59365-5030
<b>Route of Administration</b>	VAGINAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OXYQUINOLINE SULFATE</b> (UNII: 61VUG75Y3P) (OXYQUINOLINE - UNII:5UTX5635HP)	OXYQUINOLINE	0.25 mg in 1 g
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J) (LAURYL SULFATE - UNII:DIQ16UC154)	SODIUM LAURYL SULFATE	0.1 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	

TROLAMINE (UNII: 9O3K93S3TK)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59365-5030-0	113.4 g in 1 TUBE; Type 0: Not a Combination Product	04/01/1977	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		04/01/1977	

**Labeler** - CooperSurgical, Inc. (801895244)

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CooperSurgical, Inc.