

**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.

Trimo San

Manufactured for:

CooperSurgical Company

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MX5030 MILEX® TRIMO-SAN™ FOR PESSARY WEARERS

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 (2g) of TRIMO-SAN 3 times the first week after original insertion of pessary.
- Use TRIMO-SAN ½ (2g) 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 UNIVERSAL APPLICATOR

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 the universal applicator to TRIMO-SAN tube (see picture 1).
4. While holding the Universal Applicator, squeeze the tube from the bottom until TRIMO-SAN reaches the specified dosage level (see picture 2).

5. Detach the Universal Applicator from the tube. Gently insert the Universal Applicator approximately ½ inch into the vagina.

Press in the plunger of the Universal Applicator to dispense the gel.

Keep the plunger pressed until the Universal Applicator 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 the Universal Applicator immediately after using by flushing the Universal Applicator (pull and press plunger back and forth) several times, holding the Universal Applicator under water (see picture 3).

Make sure that the Universal Applicator is clean and dry before reusing.

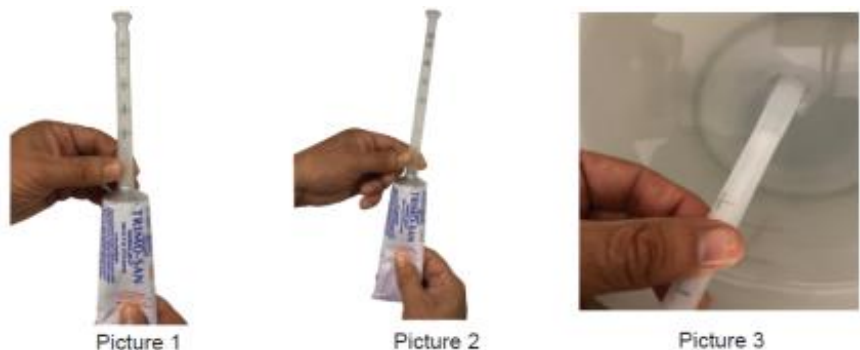
7. After each use, wipe threads of tube and inside of cap. Recap tightly.

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.



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PRINCIPAL DISPLAY PANEL

NDC 59365-5030-0

TRIMO-SAN

VAGINAL JELLY SET

with Universal Applicator

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

Rx Only



Revised: 6/2022

TRIMO SAN			
oxyquinoline sulfate and sodium lauryl sulfate jelly			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:59365-5030
Route of Administration	VAGINAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
OXYQUINOLINE SULFATE (UNII: 61VUG75Y3P) (OXYQUINOLINE - UNII:5UTX5635HP)		OXYQUINOLINE	0.25 mg in 1 g
SODIUM LAURYL SULFATE (UNII: 368GB5141J) (LAURYL SULFATE - UNII:DIQ16UC154)		SODIUM LAURYL SULFATE	0.1 mg in 1 g
Inactive Ingredients			
Ingredient Name			Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			

SODIUM CITRATE (UNII: 1Q73Q2JULR)

METHYLPARABEN (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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