TRIMO-SAN- oxyquinoline sulfate and sodium lauryl sulfate jelly Denison Pharmaceuticals, LLC

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

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.

TRIMO-SAN and PREGNANCY

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

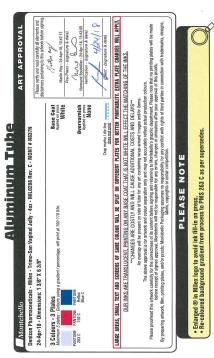
- CooperSurgical does not recommend the use of **TRIMO-SAN** during pregnancy.
- If you wish to become pregnant, do not use **TRIMO-SAN** or any other personal hygiene product vaginally (douches, vaginal sprays, jellies or suppositories), for 6 hours prior to or following intercourse. Any product used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

GENERAL INFORMATION

Use Cap to pierce seal in head of tube
Instructions for use inside package
Keep this product out of the reach of children

PRINCIPAL DISPLAY PANEL





TRIMO-SAN

oxyquinoline sulfate and sodium lauryl sulfate jelly

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0295-5030
Route of Administration	VAGINAL		

l	Active Ingredient/Active Moiety				
l	Ingredient Name	Basis of Strength	Strength		
	OXYQUINOLINE SULFATE (UNII: 61VUG75Y3P) (OXYQUINOLINE - UNII:5UTX5635HP)	OXYQUINOLINE	0.25 mg in 1 g		
	SO DIUM LAURYL SULFATE (UNII: 368GB5141J) (LAURYL SULFATE - UNII:DIQ 16 UC 154)	SODIUM LAURYL SULFATE	0.1 mg in 1 g		

Inactive Ingredients		
Ingredient Name	Strength	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)		
METHYLPARABEN (UNII: A2I8C7HI9T)		

TROLAMINE (UNII: 9O3K93S3TK)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
CARBOMER 934 (UNII: Z135WT9208)	
WATER (UNII: 059QF0KO0R)	

	Packaging			
i	# Item Code Package Description		Marketing Start Date	Marketing End Date
	NDC:0295-5030-18	113.4 g in 1 TUBE; Type 0: Not a Combination Product	09/16/2019	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		09/16/2019		

Labeler - Denison Pharmaceuticals, LLC (001207208)

Establishment				
Name	Address	ID/FEI	Business Operations	
Denison Pharmaceuticals, LLC		001207208	manufacture(0295-5030)	

Revised: 9/2019 Denison Pharmaceuticals, LLC