

RELEGARD- glacial acetic acid, oxyquinoline gel
BLANSETT PHARMACAL CO

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](#).

RELEGARD THERAPEUTIC VAGINAL GEL WITH APPLICATOR

DOSAGE AND ADMINISTRATION

TO OPEN: USE TOP OF CAP TO TWIST OFF SEAL.

FOR VAGINAL USE ONLY.

CONTAINS: GLACIAL ACETIC ACID 0.9%, OXYQUINOLINE 0.025%, PRESERVATIVE, GLYCERIN, LACTIC ACID BUFFER, POLYETHYLENE GLYCOL 4500 AND PURIFIED WATER. THE PH OF 3.8 - 4.3 IS ADJUSTED USING 1N POTASSIUM HYDROXIDE.

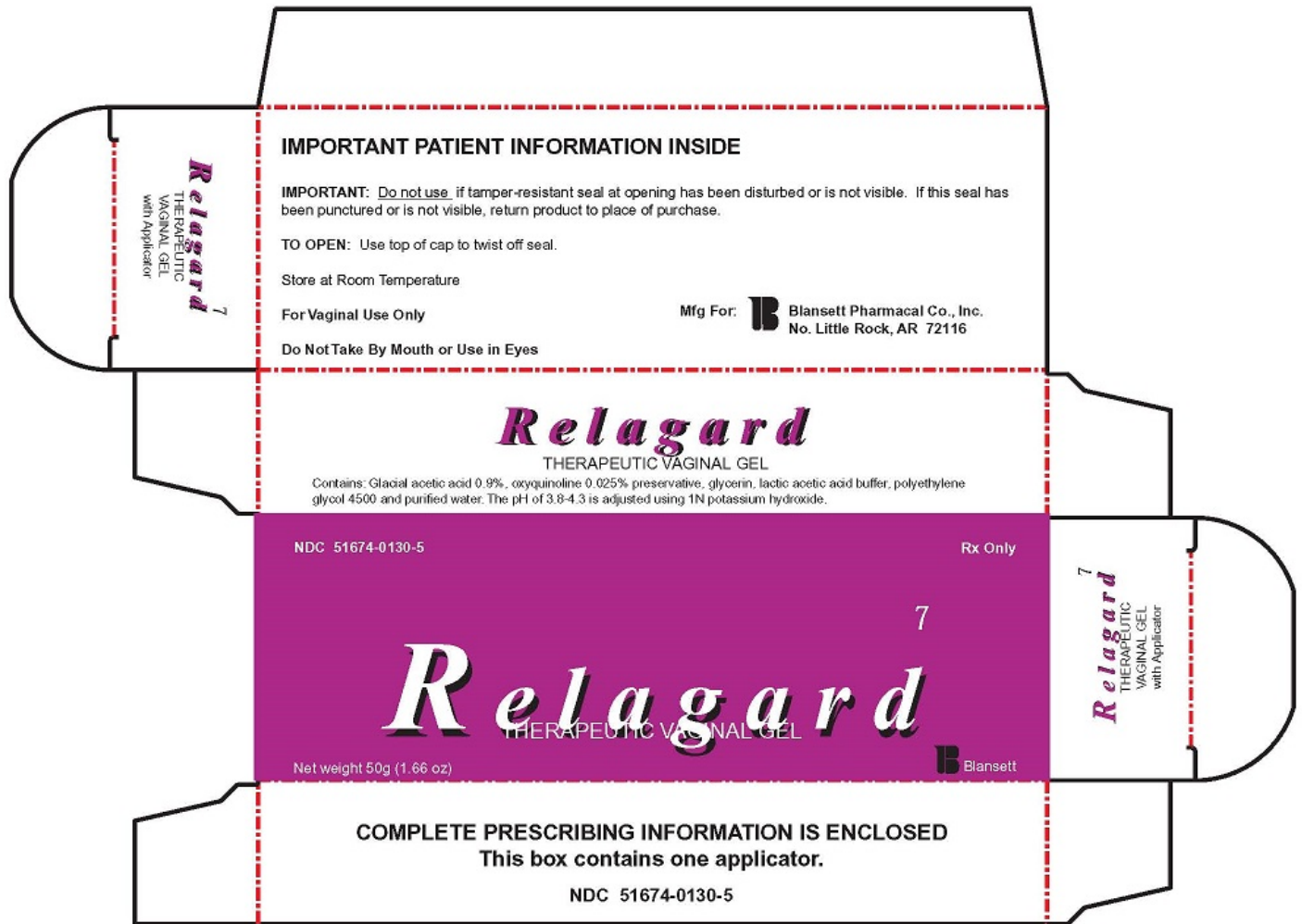
DO NOT USE IF TAMPER-RESISTANT SEAL AT OPENING HAS BEEN DISTURBED OR IS NOT VISIBLE. IF THIS SEAL HAS BEEN PUNCTURED OR IS NOT VISIBLE, RETURN PRODUCT TO PLACE OF PURCHASE.

STORE AT ROOM TEMPERATURE.

DO NOT TAKE BY MOUTH OR USE IN EYES.

COMPLETE PRESCRIBING INFORMATION IS ENCLOSED.

THIS BOX CONTAINS ONE APPLICATOR.



RELEGARD

glacial acetic acid, oxyquinoline gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:51674-0130
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETIC ACID (UNII: Q40Q9N063P) (ACETIC ACID - UNII:Q40Q9N063P)	ACETIC ACID	0.9 mg in 1 mL
OXYQUINOLINE (UNII: 5UTX5635HP) (OXYQUINOLINE - UNII:5UTX5635HP)	OXYQUINOLINE	0.025 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
LACTIC ACID (UNII: 33X04XA5AT)	
POLYETHYLENE GLYCOL 4500 (UNII: TVH7653921)	
WATER (UNII: 059QF0K00R)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51674-0130-5	50 mL in 1 TUBE; Type 0: Not a Combination Product	03/20/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/20/2017	

Labeler - BLANSETT PHARMACAL CO (037477378)**Establishment**

Name	Address	ID/FEI	Business Operations
BLANSETT PHARMACAL CO		037477378	manufacture(51674-0130)

Revised: 3/2017

BLANSETT PHARMACAL CO