

PRED-GATI- prednisolone-gatifloxacin suspension
Imprimis Rx NJ

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.

Store at 20° to 25° C (68° to 77° F)

Bottle Label

	<p>Sterile 3.5 ml Bottle</p> <p>NDC 70261-502-03</p> <p style="background-color: #0070C0; color: white; padding: 5px;">Prednisolone-Gatifloxacin 1%/0.5%</p> <p style="background-color: black; color: white; padding: 2px;">Shake Well Before Use</p> <p>Ophthalmic Suspension</p> <p>Compounded for a licensed professional or patient use by</p> <p style="font-size: 2em; font-weight: bold; letter-spacing: -0.5em;">imprimis^{Rx}</p> <p>1705 Route 46 West, Suite 4 LedgeWood, NJ 07852 (973)328-8756</p>	<p>Each mL contains: Prednisolone Acetate, Gatifloxacin, Sodium Chloride, Polysorbate 80, Poloxamer 407NF, Edetate Disodium, Sodium Phosphate Monobasic Anhydrous, Sodium Phosphate Dibasic Heptahydrate, Benzalkonium Chloride 50% and Sterile Water.</p> <p>Sodium Hydroxide and/or Hydrochloric Acid may have been used to adjust pH.</p> <p>Store at controlled room temperature 20-25°C (68 -77°F)</p> <p>This medicine was compounded for you at the direction of your prescriber. Rx Only - not for resale</p> <p>Lot# XXXXXXXXXXXXX</p> <p>Use by:</p>
-----------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

PRED-GATI			
prednisolone-gatifloxacin suspension			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70261-502
Route of Administration	OPHTHALMIC		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	PREDNISOLONE ACETATE (UNII: 8B2807733D) (PREDNISOLONE - UNII:9PHQ9Y1OLM)	PREDNISOLONE ACETATE	10 mg in 1 mL
	GATIFLOXACIN HEMIHYDRATE (UNII: AN201CY09J) (GATIFLOXACIN - UNII:L4618BD7KJ)	GATIFLOXACIN HEMIHYDRATE	5 mg in 1 mL
Inactive Ingredients			
	Ingredient Name	Strength	
	SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE (UNII: 70WT22SF4B)	1.9 mg in 1 mL	
Packaging			
#	Item Code	Package Description	Marketing Start Date
			Marketing End Date

1	NDC:70261-502-03	3.5 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	03/01/2018	
---	------------------	----------------------------------------------------------------	------------	--

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/01/2018	

Labeler - ImprimisRx NJ (931390178)

Revised: 2/2018

ImprimisRx NJ