PRED-GATI- prednis olone-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.

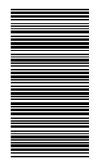
Store at 20° to 25° C (68° to 77° F)

Bottle Label

Sterile 3.5 ml Bottle

NDC 70261-502-03

Prednisolone-Gatifloxacin 1%/0.5%



Shake Well Before Use

Ophthalmic Suspension

Compounded for a licensed professional or patient use by

<u>imprimis</u> _R

1705 Route 46 West, Suite 4 Ledgewood, NJ 07852 (973)328-8756

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.

Sodium Hydroxide and/or Hydrochloric Acid may have been used to adjust pH. Store at controlled room temperature 20-25°C (68 -77°F) This medicine was compounded for you at the direction of your prescriber. Rx Only - not for resale

Lot# XXXXXXXXXXX Use by:

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 PREDNISOLONE ACETATE (UNII: 8B2807733D) (PREDNISOLONE UNII:9PHQ9Y10LM) GATIFLOXACIN HEMIHYDRATE (UNII: AN201CY09J) (GATIFLOXACIN UNII:14618BD7KJ) GATIFLOXACIN HEMIHYDRATE Strength O mg in 1 mL GATIFLOXACIN HEMIHYDRATE

Inactive Ingredients	
Ingredient Name	Strength
SODIUM PHO SPHATE, DIBASIC, HEPTAHYDRATE (UNII: 70 WT22SF4B)	1.9 mg in 1 mL

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date

	3.5 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	0 3/0 1/20 18			
Marketing Information					
Marketing Catego	ry Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
unapproved drug othe	r	0 3/0 1/20 18			

Labeler - Imprimis Rx NJ (931390178)

Revised: 2/2018 ImprimisRx NJ