PRED-GATI- prednisolone-gatifloxacin suspension
ImprimisRx 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

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