

PRED-GATI-BROM- prednisolone-gatifloxacin-bromfenac suspension/ drops
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)

<p>Sterile 3.5 ml Bottle</p> <p>Prednisolone-Gatifloxacin-Bromfenac 1%/0.5%/0.075%</p> <p>Shake Well Before Use</p> <p>Ophthalmic Drops</p> <p>Compounded for a licensed professional for patient use by</p> <p>imprimis Rx</p> <p>Imprimis RX NJ 1705 Route 46 West, Suite 4 Ledgewood, NJ 07852 (973)328-8756</p>	<p>NDC 70261-504-03</p>	<p>Each mL contains: Prednisolone Acetate 10mg, Gatifloxacin Sesquihydrate 5 mg, Bromfenac Sodium 0.75mg, Sodium Chloride, Polysorbate 80, Poloxamer 407, Edetate Disodium, Sodium Phosphate Monobasic Anhydrous, Sodium Phosphate Dibasic Heptahydrate, Benzalkonium Chloride 50% and Sterile Water q.s. Sodium Hydroxide may have been used to adjust pH.</p> <p>Store at controlled room temperature 20-25°C (68 -77°F). This medicine was compounded for you at the direction of your prescriber. Protect from light. Rx Only - Not for resale</p> <p>Lot# xxxxxxxxxxxx</p> <p>Use By: xxxxxxxxxxxx</p>
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PRED-GATI-BROM				
prednisolone-gatifloxacin-bromfenac suspension/ drops				
Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70261-504	
Route of Administration	OPHTHALMIC			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	GATIFLOXACIN HEMIHYDRATE (UNII: AN201CY09J) (GATIFLOXACIN - UNII:L4618BD7KJ)	GATIFLOXACIN HEMIHYDRATE	5 mg in 1 mL	
	BROMFENAC (UNII: 864P0921DW) (BROMFENAC - UNII:864P0921DW)	BROMFENAC	0.75 mg in 1 mL	
	PREDNISOLONE ACETATE (UNII: 8B2807733D) (PREDNISOLONE - UNII:9PHQ9YIOLM)	PREDNISOLONE ACETATE	10 mg in 1 mL	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70261-504-03	3.5 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	01/01/2018	
Marketing Information				

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

Labeler - ImprimisRx NJ (931390178)

Revised: 2/2018

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