

**MYDRIATIC-4- tropicamide - proparacaine - phenylephrine - ketorolac solution/ drops**  
**Imprimis NJOF, LLC**

*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.*

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**Store at 20° to 25° C (68° to 77° F)**

**NDC 71384-632-05**

**Tropicamide-Proparacaine-Phenylephrine-Ketorolac**

**5mL Ophthalmic Drops (1/0.5/2.5/0.5)%**

**Lot:** XXXXXX

**Date Compounded:** DDMMYYYY

**Expires on:** DDMMYYYY

**Imprimis** <sup>Rx</sup>

Imprimis NJOF, LLC.  
 1705 Route 46 West, Unit 6B  
 Ledgewood, NJ 07852  
 (844)446-6979

Active Ingredients (per mL)  
 Tropicamide 10mg  
 Proparacaine HCL 5mg  
 Phenylephrine HCL 25mg  
 Ketorolac Tromethamine 5mg

Inactive Ingredients (per mL)  
 Edetate Calcium Disodium 1mg, Benzalkonium Chloride 50% NF 0.0002mL, Sodium Metabisulfite 2mg, Hydrochloric Acid and/or Sodium Hydroxide to adjust pH.



Store at 20 to 25°C

Rev. 0

In case of adverse event contact:  
[www.fda.gov/medwatch](http://www.fda.gov/medwatch) or (800) FDA1088

This is a compounded drug.  
 NOT FOR RESALE  
 OFFICE USE ONLY

**MYDRIATIC-4**

tropicamide - proparacaine - phenylephrine - ketorolac solution/ drops

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:71384-632
<b>Route of Administration</b>	OPHTHALMIC		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>TROPICAMIDE</b> (UNII: N0A3Z5XTC6) (TROPICAMIDE - UNII:N0A3Z5XTC6)	TROPICAMIDE	10 mg in 1 mL
<b>KETOROLAC TROMETHAMINE</b> (UNII: 4EVE5946BQ) (KETOROLAC - UNII:YZI5105V0L)	KETOROLAC TROMETHAMINE	5 mg in 1 mL
<b>PROPARACAINE HYDROCHLORIDE</b> (UNII: U96OL57GOY) (PROPARACAINE - UNII:B4OB0JHI1X)	PROPARACAINE HYDROCHLORIDE	5 mg in 1 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	25 mg in 1 mL

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71384-632-05	5 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	05/01/2018	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/01/2018	

**Labeler** - Imprimis NJOF, LLC (080431967)

Revised: 5/2018

Imprimis NJOF, LLC