IXOBA M- moxifloxacin 0.5%, ketorolac 0.5%, prednisolone acetate 1%
Brisk Pharmaceuticals, Inc.

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.

IXOBA M

Rx Only

NDC 73614-454-03

For Use in Eyes Only

IXOBA M

Each Pack Contains:

Moxifloxacin 0.5% Ophthalmic Solution - 3ml

Ketorolac 0.5% Ophthalmic Solution - 5ml

Prednisolone Acetate 1% Ophthalmic Suspension - 5ml

Brisk Pharmaceuticals

See Instructions on the bottom of the package

What is Ixoba M used for: Ixoba M is a convenient pack containing 3 ophthalmic medication bottles.

How Supplied: Ixoba M is supplied as a co-pack containing Moxifloxacin 0.5% Ophthalmic Suspension 3ml bottle, Ketorolac 0.5% Ophthalmic Suspension 5ml bottle, Prednisolone Acetate 1% Ophthalmic Suspen-sion 5ml bottle.

Storage: Store at 20C to 25C (68F-77F). Protect from light.

Please read the leaflet inside each bottle for 'full prescribing information' about that medication.

Patient Counseling Information:

Risk of Contamination: Do not touch the dropper tip to any surface to avoid contaminating the contents by common bacteria known to cause ocular infections.

Concomitant Use of Contact Lenses: Do not administer Moxifloxacin Ophthalmic Suspension, Ketorolac Ophthalmic Suspension or Prednisolone Acetate Ophthalmic Suspension while wearing contact lenses.

Concomitant Topical Ocular Therapy: If more than one topical ophthalmic medication is being used, the medications should be administered at least 5 minutes apart.

For questions on Ixoba M, please call your Ophthalmologist Office or Ixoba Assist at 469-342-1471.

Keep out of the reach of children.

TAMPER EVIDENT: Do not use the individual eye drops inside the pack if the seal on its carton is broken or missing.

Lot: See the lot number on each individual bottle inside the pack.

Exp: See the expiration date on each individual bottle inside the pack.

Packaged By: Unit Dose Solutions Inc., Morrisville, NC 27560

Packaged for: Brisk Pharmaceuticals, Dallas, TX 75217

IXOBA M™

MEDICATION INSTRUCTIONS

Patient Name:_____ **Date:** _____

Select the appropriate instructions to use for each medication

Moxifloxacin 0.5% Ophthalmic Solution - 3ml
Instill __ drop(s) in ☐ affected eye ☐ both eyes ☐ 1 ☐ 2 ☐ 3 ☐ 4 times daily
as directed for ☐ 1 ☐ 2 ☐ 3 weeks

Prednisolone Acetate 1% Ophthalmic Suspension - 5ml
Instill __ drop(s) in ☐ affected eye ☐ both eyes ☐ 1 ☐ 2 ☐ 3 ☐ 4 times daily
as directed for ☐ 1 ☐ 2 ☐ 3 weeks

Ketorolac Tromethamine 0.5% Ophthalmic Solution - 5ml
Instill __ drop(s) in ☐ affected eye ☐ both eyes ☐ 1 ☐ 2 ☐ 3 ☐ 4 times daily
as directed for ☐ 1 ☐ 2 ☐ 3 weeks

See reverse side for more information

IXOBA M™

What is Ixoba M:
Ixoba M is a convenient co-pack containing 3 ophthalmic medication bottles.

How Supplied:
Ixoba M is supplied as a co-pack containing Moxifloxacin 0.5% Ophthalmic Solution 3ml bottle, Prednisolone Acetate 1% Ophthalmic Suspension 5ml bottle and Ketorolac Tromethamine 0.5% Ophthalmic Solution 5ml bottle.

Storage: Store at 20C to 25C (68F-77F). Protect from light.

Please read the leaflet inside each bottle for 'full prescribing information'.

For questions on Ixoba M, please call your Ophthalmologist Office or Ixoba Assist at 469-342-1471.

Brisk Pharmaceuticals www.ixoba.com

IXOBA M

moxifloxacin 0.5%, ketorolac 0.5%, prednisolone acetate 1% kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:73614-454

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73614-454-03	1 in 1 CARTON; Type 1: Convenience Kit of Co-Package	08/26/2021	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	5 mL
Part 2	1 BOTTLE	5 mL
Part 3	1 BOTTLE	3 mL

Part 1 of 3

KETOROLAC TROMETHAMINE

ketorolac tromethamine solution

Product Information	
Item Code (Source)	NDC:61314-126
Route of Administration	OPHTHALMIC

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
KETOROLAC TROMETHAMINE (UNII: 4EVE5946BQ) (KETOROLAC - UNII:YZI5105V0L)	KETOROLAC	5 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		5 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076583	11/05/2009	

Part 2 of 3

PREDNISOLONE ACETATE

prednisolone acetate suspension/ drops

Product Information

Item Code (Source)	NDC:60758-119
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

Inactive Ingredients

Ingredient Name	Strength
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0KO0R)	
SODIUM BISULFITE (UNII: TZX5469Z6I)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
BORIC ACID (UNII: R57ZHV85D4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		5 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
NDA authorized generic	NDA017011	08/19/1997	

Part 3 of 3

MOXIFLOXACIN

moxifloxacin solution/ drops

Product Information

Item Code (Source)	NDC:68180-422
Route of Administration	OPHTHALMIC

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MOXIFLOXACIN HYDROCHLORIDE MONOHYDRATE (UNII: B8956S8609) (MOXIFLOXACIN - UNII:U188XYD42P)	MOXIFLOXACIN	5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BORIC ACID (UNII: R57ZHV85D4)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	yellow (Yellow Colored Transparent)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		3 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202867	07/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/26/2021	

Labeler - Brisk Pharmaceuticals, Inc. (117250794)

Establishment

Name	Address	ID/FEI	Business Operations
Unit Dose Solutions, Inc		360804194	repack(73614-454)

Revised: 11/2021 Brisk Pharmaceuticals, Inc.