**STRENZA- moxifloxacin 0.5%, ketorolac tromethamine 0.5%, prednisolone acetate 1%**
**Brisk Pharmaceuticals**

*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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**STRENZA**

Rx Only

NDC 73614-731-03

For Use in Eyes Only

STRENZA tm

Each Pack Contains:

Moxifloxacin Ophthalmic Solution, USP 0.5% - 3ml Bottle

Ketorolac Tromethamine Ophthalmic Solution, 0.5% - 5ml Bottle
Prednisolone Acetate Ophthalmic Suspension, USP 1% - 5ml Bottle

Brisk Pharmaceuticals

**Keep out of the reach of children.**

**TAMPER EVIDENT:** Do not use the individual eye drops inside the pack if the seal on its bottle 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
**Distributed by:**
Brisk pharmaceuticals,
Richardson, TX 75081

**Patient Information:**
**What is Strenza:** Strenza is a convenient pack containing 3 ophthalmic medication bottles.

**How Supplied:** Strenza is supplied as a pack containing Moxifloxacin Ophthalmic Solution, USP 0.5% - 3ml Bottle, Ketorolac Tromethamine Ophthalmic Solution, 0.5% - 5ml Bottle, Prednisolone Acetate Ophthalmic Suspension, USP 1% - 5ml Bottle.

**Storage:** Store at 20°C to 25°C (68°F-77°F).

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

**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 topical ophthalmic medication 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.

Users are encouraged to report adverse events to FDA MedWatch 1-800-FDA-1088 or visit http://www.fda.gov/Safety/MedWatch/HowToReport/ucm053074.htm


# STRENZA

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

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:73614-731 |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:73614-731-03 | 1 in 1 CARTON; Type 1: Convenience Kit of Co-Package | 10/16/2024 | |

| Quantity of Parts | | |
|---|---|---|
| **Part #** | **Package Quantity** | **Total Product Quantity** |
| **Part 1** | 1 BOTTLE, DROPPER | 5 mL |
| **Part 2** | 1 BOTTLE, PLASTIC | 5 mL |
| **Part 3** | 1 BOTTLE | 3 mL |

## Part 1 of 3

## KETOROLAC TROMETHAMINE

ketorolac tromethamine solution/ drops

| Product Information | |
|---|---|
| **Item Code (Source)** | NDC:69315-322 |
| **Route of Administration** | OPHTHALMIC |

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

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **OCTOXYNOL-40** (UNII: 9T1C662FKS) | |
| **HYDROCHLORIC ACID** (UNII: QTT17582CB) | |
| **SODIUM HYDROXIDE** (UNII: 55X04QC32I) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **BENZALKONIUM CHLORIDE** (UNII: F5UM2KM3W7) | |
| **EDETATE DISODIUM** (UNII: 7FLD91C86K) | |
| **SODIUM CHLORIDE** (UNII: 451W47IQ8X) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | | 5 mL in 1 BOTTLE, DROPPER; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.) | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA218204 | 06/01/2024 | |

## Part 2 of 3

# PREDNISOLONE ACETATE

prednisolone acetate suspension/ drops

| Product Information | |
|---|---|
| **Item Code (Source)** | NDC:61314-637 |
| **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** |
| **BENZALKONIUM CHLORIDE** (UNII: F5UM2KM3W7) | |
| **POLYSORBATE 80** (UNII: 6OZP39ZG8H) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **SODIUM HYDROXIDE** (UNII: 55X04QC32I) | |
| **CITRIC ACID MONOHYDRATE** (UNII: 2968PHW8QP) | |
| **EDETATE DISODIUM** (UNII: 7FLD91C86K) | |
| **HYPROMELLOSE, UNSPECIFIED** (UNII: 3NXW29V3WO) | |
| **SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM** (UNII: GR686LBA74) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |

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

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| NDA authorized generic | NDA017469 | 12/15/1994 | |

## 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) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **SODIUM HYDROXIDE** (UNII: 55X04QC32I) | |

| 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** | | 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 | Application Number or Monograph | Marketing Start | Marketing End |
|---|---|---|---|

| Category | Citation | Date | Date |
|---|---|---|---|
| unapproved drug other | | 10/16/2024 | |

## Labeler - Brisk Pharmaceuticals (117250794)

Revised: 10/2024 Brisk Pharmaceuticals