TAFLUPROST- tafluprost solution
The Ritedose Corporation

Tafluprost Ophthalmic Solution, 0.0015%

NDC 0781-6184-87

Tafluprost Ophthalmic Solution 0.0015%

Single-Use Containers

Preservative-Free, Sterile

For Topical Application in the Eye

REFRIGERATE (2° to 8°C or 36° to 46°F)

Rx Only

30 Single-Use Containers:

6 Pouches x 5 Single-Use Containers

(0.3 mL each)

Sandoz A Novartis Division

Tafluprost Ophthalmic Solution, 0.0015% Carton


NDC 0781-6184-87
Tafluprost
Ophthalmic Solution
0.0015%
Single-Use Containers
Preservative-Free, Sterile
For Topical Application in the Eye
REFRIGERATE (2° to 8°C or 36° to 46°F)
Rx Only
30 Single-Use Containers:
6 Pouches x 5 Single-Use Containers
(0.3 mL each)
SANDOZ A Novartis Division
For Topical Application in the Eye
Usual Dosage:
One drop in the affected eye(s) once daily in the evening. The solution from one single-use container is to be used immediately after opening for administration to one or both eyes.
Storage:
Store refrigerated at 2° to 8°C (36° to 46°F). Store in original pouch. After the pouch is opened, the single-use containers may be stored in the opened foil pouch for up to 30 days at room temperature 20° to 25°C (68° to 77°F). Protect from moisture.
ATTENTION:
Use the eye drops immediately after opening the container. Discard the opened container with any remaining contents immediately after use.
KEEP OUT OF THE REACH OF CHILDREN.
RPSC0449
LBL0056600
N 3 0781-6184-87 1
Manufactured by
The Ritedose Corporation
Columbia, SC 29203 for
Sandoz Inc., Princeton, NJ 08540
Product of India
Rev. 02/2022
Shipping Instructions:
During shipment to the patient, Tafluprost Ophthalmic Solution may be maintained at temperatures up to 40°C (104°F) for a period not exceeding 2 days.
IMPORTANT INFORMATION FOR MAIL-ORDER PATIENTS: Contact dispensing pharmacy if prescription is not received within 2 days of dispensing date.
SEE DATE ON PRESCRIPTION LABEL.
Mail-order prescription received after two days of the dispensing date noted on the prescribing label should not be used.
P/N RPSC0449
SC 113515
FOLD
NDC 0781-6184-87
Tafluprost
Ophthalmic Solution
0.0015%
For Topical Application in the Eye
Rx Only
Contains:
Active: Tafluprost 0.0015% (4.5 mcg per single-use container)
Inactive ingredients: glycerol, sodium dihydrogen phosphate dihydrate, disodium edetate, polysorbate 80, Water for Injection. Hydrochloric acid and/or sodium hydroxide are added to adjust pH.
Single-Use Containers
Preservative-Free, Sterile
REFRIGERATE (2° to 8°C or 36° to 46°F)
30 Single-Use Containers:
6 Pouches x 5 Single-Use Containers
(0.3 mL each)
SANDOZ A Novartis Division

TAFLUPROST

tafluprost solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65302-062
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TAFLUPROST (UNII: 1O6WQ6T7G3) (TAFLUPROST - UNII:1O6WQ6T7G3)	TAFLUPROST	0.0045 mg in 0.3 mL

Inactive Ingredients	
Ingredient Name	**Strength**
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM PHOSPHATE, MONOBASIC, DIHYDRATE (UNII: 5QWK665956)	
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65302-062-05	6 in 1 CARTON	12/05/2022	
1		5 in 1 POUCH		
1		0.3 mL in 1 AMPULE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209040	12/05/2022	

Labeler - The Ritedose Corporation (837769546)

Establishment

Name	Address	ID/FEI	Business Operations
The Ritedose Corporation		837769546	analysis(65302-062) , label(65302-062) , manufacture(65302-062) , pack(65302-062)