

Alcon [®] PACKAGING			
FILE NAME: AAA2224 L BMTPT 2_5ML		COLORS: BLACK (b) (4) COATING NOTATIONS -DIE VINYL	
ARTIST: (b) (4)	SIGNATURE: _____	REV: C	DATE: 02/02/13
DIMENSIONS / DRAWING NUMBER: _____		SPECIAL INSTRUCTIONS: _____	
Alcon [®] PROOFREADING REPORT			
☐ Docuproof System ☐ Proofreading ☐ Text Verification System (TVS) ☐ SRS Compare		APPROVALS: ☐ Approved ☐ Correct & Return	
TYPE OF INSPECTION: ☐ Electronic / Electronic ☐ Hardcopy / Hardcopy # of Images: _____		SETTINGS: Dimmer: _____ Aperture: _____ Zoom: _____ Focus: _____	
INSPECTION RESULTS: # of Errors: _____		SIGNATURE: _____ DATE: _____	



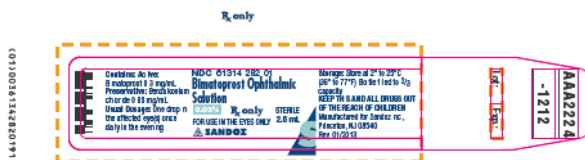
1. TEXT, COLOR & COATING AREA.
2. COLOR & COATING AREA, NO TEXT ALLOWED.
3. DWG. NO AND CONTROL DATE LOCATION.
4. QUIET AREA - NO TEXT, COLOR OR COATING ALLOWED, EXCEPT AS INDICATED.
5. PREPRINTED "LOT:" LOCATION.
6. PREPRINTED "EXP.:" LOCATION.

AA0975--

LBLPS, SAMPLE BOTTLE	
PKG. ENG. USE ONLY	
A00975--	
04/08/98	
(b) (4)	
APPROVAL:	
Z00100B	(b) (4) 04/09/98
PKG/DATE:	(b) (4) 4/09/98
PKG/DATE:	(b) (4) 4/09/98



SCALE: 2X



Alcon [®] PACKAGING			
FILE NAME: AAA2225 L BMTPTST 5ML		COLORS: (b) (4)	
ARTIST: (b) (4)	SIGNATURE: _____	REV: E	DATE: 02/01/13
DIMENSIONS / DRAWING NUMBER: _____		COATING NOTATIONS -DIE VINYL	
SPECIAL INSTRUCTIONS: _____		5:22 pm, Feb 01, 2013	

Alcon [®] PROOFREADING REPORT			
☐ Docuproof System		APPROVALS:	
☐ Proofreading		☐ Approved	
☐ Text Verification System (TVS)		☐ Correct & Return	
☐ SRS Compare		SIGNATURE: _____	
TYPE OF INSPECTION:		SETTINGS:	INSPECTION RESULTS:
☐ Electronic / Electronic		Dimmer: _____	# of Errors: _____
☐ Hardcopy / Hardcopy		Aperture: _____	
_____ # of Images		Zoom: _____	
		Focus: _____	
			DATE: _____

LBLPS, LINES 15/16, 5ML

PKG. ENG. USE ONLY	
L00858BD	
12/13/98	"BLACK INK" WAS
"BLACK OR HIGH CONTRAST"	

UNLESS OTHERWISE SPECIFIED:
TOLERANCE: $\pm 1/32"$

(b) (4)

APPROVAL:

Z00100A-

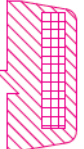
PKG/DATE:

PKG/DATE:

(b) (4)

12/14/98

12/18/98

1011003114480031		Contains Active: Bimatoprost 0.3 mg/mL Preservative: Benzalkonium chloride 0.05 mg/mL Usual Dosage: One drop in the affected eye(s) once daily in the evening Storage: Store at 2° to 25°C (36° to 77°F) Sterile / Not to 45 capacity		NDC 61314-282-03 Bimatoprost Ophthalmic Solution  FOR USE IN THE EYES ONLY Rx only STERILE 5 mL	KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN Manufactured by Alcon Laboratories, Inc. Fort Worth TX, 76134 Rev 12/2012		AAA2225-1212

Alcon [®] PACKAGING			
FILE NAME: AAA2226 L BMTPTST 7_5ML			
ARTIST:	SIGNATURE:	REV:	DATE:
(b) (4)		F	02/05/13
DIMENSIONS / DRAWING NUMBER:			
SPECIAL INSTRUCTIONS:			
COLORS: BLACK (b) (4) COATING NOTATIONS -DIE VINYL			

Alcon [®] PROOFREADING REPORT			
☐ Docuproof System			
☐ Proofreading			
☐ Text Verification System (TVS)			
☐ SRS Compare			
TYPE OF INSPECTION:		SETTINGS:	INSPECTION RESULTS:
☐ Electronic / Electronic		Dimmer: _____	# of Errors:
☐ Hardcopy / Hardcopy		Aperture: _____	
_____ # of Images		Zoom: _____	
		Focus: _____	
APPROVALS:			
☐ Approved			
☐ Correct & Return			
SIGNATURE:			
DATE:			

1. TEXT, COLOR & COATING AREA.
2. COLOR & COATING AREA, NO TEXT ALLOWED.
3. DWG. NO. & CONTROL DATE LOCATION.
4. QUIET AREA - NO TEXT, COLOR OR COATING ALLOWED, EXCEPT AS INDICATED.
5. PREPRINTED "LOT:" LOCATION.
6. PREPRINTED "EXP." LOCATION.

Alcon[®] (b) (4)

1:34 pm, Feb 05, 2013

LBLPS, LINES 15/16, 10ML

PKG. ENG. USE ONLY		
A00859-C	Z00308	
04/06/95		
CODE AREA INCREASED BY 1/16"		

(b) (4)

APPROVAL:

Z00100

PKG/DATE:

(b) (4)

4/06/95

PKG/DATE:

4/06/95

A00859-C

DRAWING NUMBER
AND CONTROL DATE
TO BE UNDERLINED.
SEE SPECIFICATION
FOR DETAILS.



SCALE: 2X



SCALE: 1X

Alcon PACKAGING		
FILE NAME: AAA2227 C BMTPTST 2_5ML		
ARTIST: (b) (4)	SIGNATURE: _____	REV: DATE: G 02/14/13
DIMENSIONS / DRAWING NUMBER: SPECIAL INSTRUCTIONS:		
COLORS: RI ACK (b) (4) COATING NOTATIONS -DIE VINYL		
Alcon PROOFREADING REPORT		
☐ Docuproof System ☐ Proofreading ☐ Text Verification System (TVS) ☐ SRS Compare TYPE OF INSPECTION: ☐ Electronic / Electronic ☐ Hardcopy / Hardcopy # of Images: _____		APPROVALS: ☐ Approved ☐ Correct & Return SIGNATURE: _____ DATE: _____
SETTINGS: Dimmer: _____ Aperture: _____ Zoom: _____ Focus: _____		INSPECTION RESULTS: # of Errors: _____

1. GLUE AREA - NO TEXT, COLOR OR COATING.
2. CODE AREA - NO TEXT OTHER THAN LOT & EXPIRES. COATING AND COLOR ARE ACCEPTABLE.
3. BAR CODE AREA - FINISHED CODE TO BE CENTERED LEFT TO RIGHT.
4. QUIET AREA - NO TEXT OR COLOR ALLOWED.
5. PREPRINTED "LOT:" LOCATION.
6. PREPRINTED "EXP:" LOCATION.

Alcon
(b) (4)
11:04 am, Feb 14, 2013

CTN/INS, 5ML	
PKG, ENG, USE ONLY	
ADD656AA	
02/04/98	UPDATED TO NEW
FORMAT (b) (4)	
APPROVAL: _____	
Z001005-	(b) (4) 03/05/98
PKG/DATE:	
PKG/DATE:	03/06/98

GRAPHICS TOP

NDC 61314-282-01

Bimatoprost Ophthalmic Solution

0.03%

SANDOZ

This package is not child-resistant
FOR USE IN THE EYES ONLY

Rx only

STERILE
2.5 mL

SANDOZ

NDC 61314-282-01

Bimatoprost Ophthalmic Solution

0.03%

SANDOZ

This package is not child-resistant
FOR USE IN THE EYES ONLY

Rx only

STERILE
2.5 mL

SANDOZ

MANUFACTURED BY
ALCON
LABORATORIES, INC.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN
Manufactured by
Alcon Laboratories, Inc.
Fort Worth, TX 76134
for
Sandoz Inc.,
Princeton, NJ 08540
AAA2227-1212
Rev. 12/2012

FOR POSITION ONLY

Contains: Active:
Bimatoprost 0.3 mg/mL
Preservative:
Benzalkonium chloride
0.05 mg/mL
Inactive: Citric acid, purified water, sodium chloride, sodium phosphate dibasic, Sodium hydroxide and/or hydrochloric acid may be added to adjust pH. The pH during its shelf life ranges from 6.8 to 7.8.
Usual Dosage: One drop in the affected eye(s) once daily in the evening.
Storage: Store at 2° to 25°C (36° to 77°F).
Note: Bottle filled to 2/3 capacity.

LOT: _____

EXP: _____

7521

Alcon PACKAGING			
FILE NAME: AAA2228 C BMTPTST 5ML			
ARTIST:	SIGNATURE:	REV:	DATE:
(b) (4)		H	03/05/13
DIMENSIONS / DRAWING NUMBER:			
SPECIAL INSTRUCTIONS:			
Alcon PROOFREADING REPORT			
☐ Docuproof System ☐ Proofreading ☐ Text Verification System (TVS) ☐ SRS Compare		APPROVALS: ☐ Approved ☐ Correct & Return SIGNATURE: DATE:	
TYPE OF INSPECTION: ☐ Electronic / Electronic ☐ Hardcopy / Hardcopy # of Images:		SETTINGS: Dimmer: _____ Aperture: _____ Zoom: _____ Focus: _____ INSPECTION RESULTS: # of Errors:	

Alcon
(b) (4)
1:16 pm, Mar 05, 2013

1. GLUE AREA - NO TEXT, COLOR OR COATING.
2. CODE AREA - NO TEXT OTHER THAN LOT & EXPIRES.
COATING AND COLOR ARE ACCEPTABLE.
3. BAR CODE AREA - FINISHED CODE TO BE
CENTERED LEFT TO RIGHT,
4. QUIET AREA - NO TEXT OR COLOR ALLOWED.
5. PREPRINTED "LOT:" LOCATION.
6. PREPRINTED "EXP.:" LOCATION.

CTN/JNS, SML	
PKG. ENG. USE ONLY	
A00656AA	
02/04/98	UPDATED TO NEW
FORMAT	
(b) (4)	
APPROVAL:	
208100-	(b) (4)
PKG/DATE:	03/05/98
PKG/DATE:	03/06/98

GRAPHICS TOP

NDC 61314-282-03

Bimatoprost Ophthalmic Solution

0.03%

SANDOZ

This package is not child-resistant
FOR USE IN THE EYES ONLY

Rx only

STERILE
5 mL

Manufactured by
Alcon Laboratories, Inc.
Fort Worth TX, 76134
for Sandoz Inc.,
Princeton, NJ 08540
Rev. 01/2013

AAA2228-1212

FOR POSITION ONLY

NDC 61314-282-03

Bimatoprost Ophthalmic Solution

0.03%

SANDOZ

This package is not child-resistant
FOR USE IN THE EYES ONLY

Rx only

STERILE
5 mL

Contains: Active:
Bimatoprost 0.3 mg/mL.
Preservative:
Benzalkonium chloride 0.05 mg/mL.
Inactive: Citric acid, purified water,
sodium chloride, sodium phosphate
dibasic. Sodium hydroxide and/or
hydrochloric acid may be added to
adjust pH. The pH during its shelf life
ranges from 6.8 to 7.8.
Usual Dosage: One drop in the
affected eye(s) once daily in the
evening.
Storage: Store at 2° to
25°C (36° to 77°F).
Note: Bottle filled to 3/4 capacity.

MANUFACTURED BY
ALCON
LABORATORIES, INC.

LOT:

EXP.:

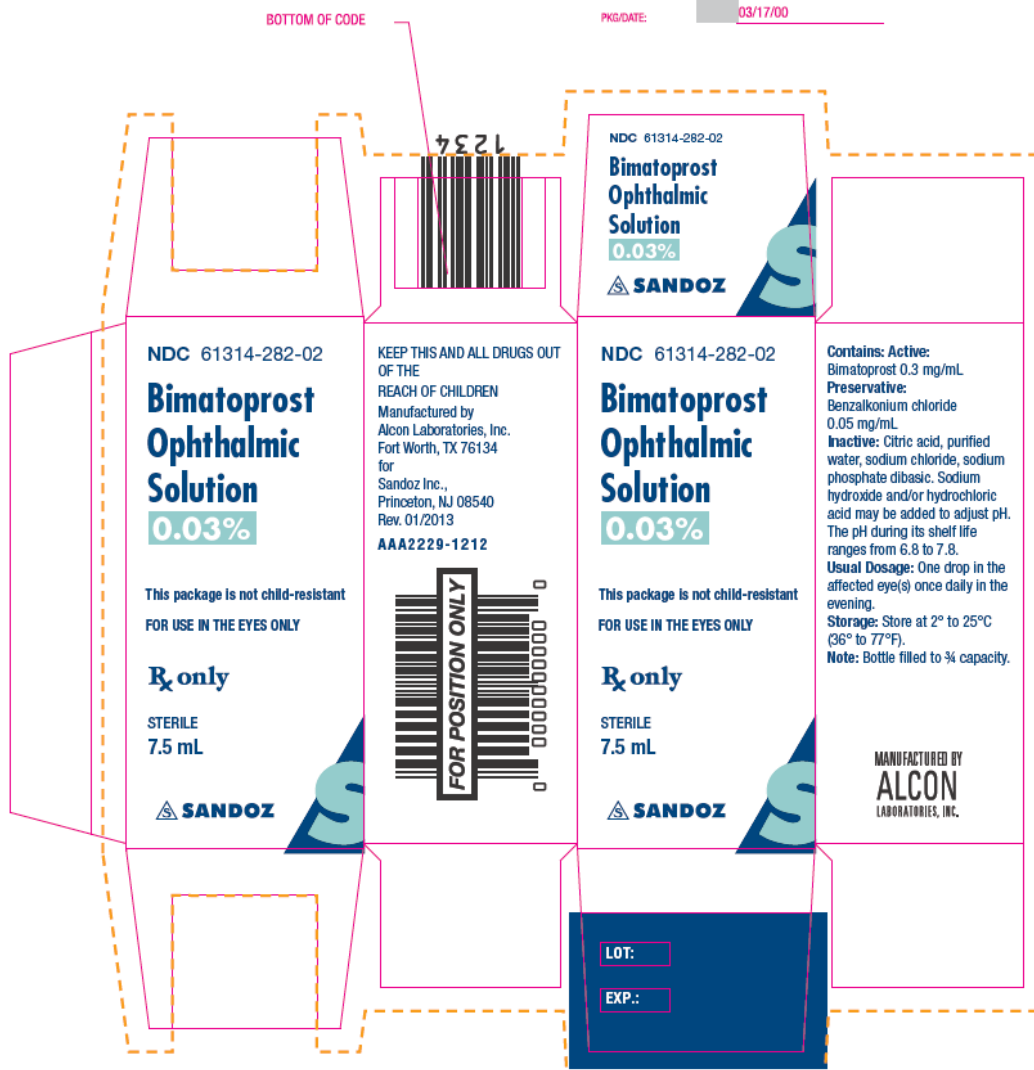
A00656AA

Alcon PACKAGING			
FILE NAME: AAA2229 C BMTPT 7_5ML			
ARTIST:	SIGNATURE:	REV:	DATE:
(b) (4)		G	02/14/13
DIMENSIONS / DRAWING NUMBER:			
SPECIAL INSTRUCTIONS:			
Alcon PROOFREADING REPORT			
☐ Docuproof System		APPROVALS:	
☐ Proofreading		☐ Approved	
☐ Text Verification System (TVS)		☐ Correct & Return	
☐ SRS Compare		SIGNATURE:	
TYPE OF INSPECTION:		DATE:	
☐ Electronic / Electronic			
☐ Hardcopy / Hardcopy			
# of Images			
SETTINGS:		INSPECTION RESULTS:	
Dimmer: _____		# of Errors:	
Aperture: _____			
Zoom: _____			
Focus: _____			

Alcon
(b) (4)
10:55 am, Feb 14, 2013

CTN/INS - 10ML	
PKG. ENCL. USE ONLY	
AO0880AA	
03/17/00	REVISED TO CURRENT
FORMAT	
(b) (4)	
APPROVAL:	
Z001008-	(b) (4)
PKG/DATE:	03/17/00
PKG/DATE:	03/17/00

1. GLUE AREA - NO TEXT, COLOR OR COATING.
2. CODE AREA - NO TEXT OTHER THAN LOT & EXPIRES.
COLOR & COATING ARE ACCEPTABLE.
3. BAR CODE AREA - FINISHED CODE TO BE
CENTERED LEFT TO RIGHT.
4. QUIET AREA - NO TEXT OR COLOR ALLOWED.
COATING IS ACCEPTABLE.
5. PREPRINTED "LOT:" LOCATION.
6. PREPRINTED "EXP:" LOCATION.



Alcon PACKAGING		Alcon PROOFREADING REPORT	
PAC NAME: 90092541 DIMPRET 03 US		INJECTION REQUEST: # of Units	
APPROVED BY: (b) (4)	DATE: 01.20.2016 10:37 AM	APPROVED BY: [Signature]	
SPECIAL INSTRUCTIONS:		REVISIONS: [Signature]	
COMMENTS: [Signature]		REVISIONS: [Signature]	

Alcon (b) (4)

10:39 am, Jan 20, 2015

DRAWING INFORMATION		
DWG NUMBER:	L00846B	REV: 0
DWG DESC.:	INSROLL, 10"X5" FOLD TO 5"X1.125"	
DWG DATE:	10/22/2012	
REV DESC.:		
DRAWN BY:	(b) (4)	

UNLESS OTHERWISE SPECIFIED:
TOLERANCE: ±1/32"

LEGEND

--- FOLD

--- CUT

2 ALCON DWG. NO. & CONTROL DATE - DIRECTION DETERMINED BY COPY.

3 NO TEXT, COLOR OR COATING

4 RESERVED FOR BAR CODE

HIGHLIGHTS OF PRESCRIBING INFORMATION	WARNINGS AND PRECAUTIONS
These highlights do not include all the information needed to use Brimonidine Ophthalmic Solution, 0.03% safely and effectively. See full prescribing information for Brimonidine Ophthalmic Solution, 0.03%.	• Pigmentation Pigmentation of the iris, periorbital tissue (eyelids) and eyelashes (eyelids) is likely to be permanent. (5.1)
Brimonidine Ophthalmic Solution, 0.03%, for topical ophthalmic use U.S. Approval: 2001	• Eyelash Changes Gradual change to eyelashes including increased length, thickness and number of lashes is likely to be permanent. (5.2)
Warnings and Precautions Intraocular Inflammation (5.3) ON/2014	ADVERSE REACTIONS Most common adverse reaction is conjunctival hyperemia (45%). (6.1) To report SUSPECTED ADVERSE REACTIONS, contact Sundt Inc., at 1-800-525-8747 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch .
INDICATIONS AND USAGE Brimonidine Ophthalmic Solution, 0.03% is a α_2 -adrenoreceptor agonist indicated for the reduction of elevated intraocular pressure in patients with open angle glaucoma or ocular hypertension. (1)	USE IN SPECIFIC POPULATIONS Use in pediatric patients below the age of 16 years is not recommended because of potential safety concerns related to increased pigmentation following long-term chronic use. (8.4)
DOSE AND ADMINISTRATION One drop in the affected eye(s) once daily in the evening. (2)	See 17 for PATIENT COUNSELING INFORMATION.
DOSE FORMS AND STRENGTHS Solution containing 0.3 mg/mL Brimonidine. (3)	Revised: 10/2014
CONTRAINDICATIONS None. (4)	
FULL PRESCRIBING INFORMATION: CONTENTS*	
1 INDICATIONS AND USAGE	10 OVERDOSAGE
2 DOSE AND ADMINISTRATION	11 DESCRIPTION
3 DOSE FORMS AND STRENGTHS	12 CLINICAL PHARMACOLOGY
4 CONTRAINDICATIONS	12.1 Mechanism of Action
5 WARNINGS AND PRECAUTIONS	12.2 Pharmacokinetics
5.1 Pigmentation	13 NONCLINICAL TOXICOLOGY
5.2 Eyelash Changes	13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
5.3 Intraocular Inflammation	14 CLINICAL STUDIES
5.4 Macular Edema	14.1 How Supplied/Storage and Handling
5.5 Bacterial Keratitis	15 PATIENT COUNSELING INFORMATION
5.6 Use with Contact Lenses	17.1 Potential for Pigmentation
6 ADVERSE REACTIONS	17.2 Potential for Eyelash Changes
6.1 Clinical Studies Experience	17.3 Avoiding the Container
6.2 Postmarketing Experience	17.4 When to Seek Physician Advice
8 USE IN SPECIFIC POPULATIONS	17.5 Use with Contact Lenses
8.1 Pregnancy	17.6 Use with Other Ophthalmic Drugs
8.2 Nursing Mothers	* Sections or subsections omitted from the full prescribing information are not listed.
8.3 Maternal Use	
8.4 Pediatric Use	
8.5 Geriatric Use	
8.6 Hepatic Impairment	
FULL PRESCRIBING INFORMATION	
INDICATIONS AND USAGE Brimonidine Ophthalmic Solution, 0.03% is indicated for the reduction of elevated intraocular pressure in patients with open angle glaucoma or ocular hypertension.	5.4 Macular Edema Macular edema, including cystoid macular edema, has been reported during the use of Brimonidine Ophthalmic Solution, 0.03% in patients with Brimonidine Ophthalmic Solution, 0.03% should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.
DOSE AND ADMINISTRATION The recommended dose is one drop in the affected eye(s) once daily in the evening. Brimonidine Ophthalmic Solution, 0.03% should not be administered more than once daily since it has been shown that more frequent administration of α_2 -adrenoreceptor agonists may decrease the intraocular pressure lowering effect. Irritation of the intraocular pressure starts approximately 4 hours after the first administration with maximum effect reached within approximately 12 hours.	5.5 Bacterial Keratitis There have been reports of bacterial keratitis associated with the use of multiple α_2 -adrenoreceptor agonist ophthalmic products. These containers have been inadvertently contaminated by patients who, in some cases, had a concurrent corneal disease or a disruption of the ocular surface barrier. See PATIENT COUNSELING INFORMATION, 17.3.
Brimonidine Ophthalmic Solution, 0.03% may be used concurrently with other topical ophthalmic drug products to lower intraocular pressure. If more than one topical ophthalmic drug is being used, the drugs should be administered at least five (5) minutes apart.	5.6 Use with Contact Lenses Contact lenses should be removed prior to instillation of Brimonidine Ophthalmic Solution, 0.03% and may be reinserted 15 minutes following instillation.
DOSE FORMS AND STRENGTHS Ophthalmic solution containing Brimonidine at 0.3 mg/mL.	ADVERSE REACTIONS
CONTRAINDICATIONS None.	6.1 Clinical Studies Experience Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice. In clinical trials, the most frequent events associated with the use of Brimonidine Ophthalmic Solution, 0.03% occurring in approximately 15% to 45% of patients, in descending order of incidence, included conjunctival hyperemia, growth of eyelashes, and ocular pain/burn. Approximately 2% of patients discontinued therapy due to conjunctival hyperemia. Ocular adverse events occurring in approximately 3 to 10% of patients, in descending order of incidence, included ocular dryness, visual disturbance, ocular burning, foreign body sensation, eye pain, pigmentation of the periorbital skin, blepharitis, cataract, superficial punctate keratitis, periorbital erythema, ocular irritation, and eyelash changes. The following ocular adverse events reported in approximately 1 to 3% of patients, in descending order of incidence, included eye discharge, tearing, photophobia, a light conjunctivitis, asthenopia, increased intraocular pigmentation, and conjunctival edema. In less than 1% of patients, intraocular inflammation was reported as follows: • Systemic adverse events reported in approximately 10% of patients were infections (primarily colds and upper respiratory tract infections). The following systemic adverse events reported in approximately 1 to 5% of patients, in descending order of incidence, included headache, chest pain, heartburn, nausea, vomiting, and dizziness. • Systemic adverse events reported in approximately 10% of patients were infections (primarily colds and upper respiratory tract infections). The following systemic adverse events reported in approximately 1 to 5% of patients, in descending order of incidence, included headache, chest pain, heartburn, nausea, vomiting, and dizziness.
WARNINGS AND PRECAUTIONS	6.2 Postmarketing Experience The following reactions have been identified during postmarketing use of Brimonidine Ophthalmic Solution, 0.03% in clinical practice. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made. The reactions, which have been chosen for inclusion due to either their seriousness, frequency of reporting, or a plausible connection to Brimonidine Ophthalmic Solution, 0.03% are a combination of these factors, include: abnormal hair growth, dizziness, eyelid edema, hyperkeratosis, nausea, and periorbital and lid changes associated with a deepening of the eyelid sulcus.
5.1 Pigmentation Brimonidine Ophthalmic Solution has been reported to cause changes to pigmentation of tissues. The most frequently reported changes have been increased pigmentation of the iris, periorbital tissue (eyelids) and eyelashes. Pigmentation is expected to increase as long as Brimonidine is administered. The pigmentation change is due to increased melanin content in the melanocytes rather than to an increase in the number of melanocytes. After discontinuation of Brimonidine, pigmentation of the iris is likely to be permanent, while pigmentation of the periorbital tissue and eyelash changes have been reported to be reversible in some patients. Patients who receive treatment should be informed of the possibility of increased pigmentation. The long term effects of increased pigmentation are not known. Iris color change may not be noticeable for several months to years. Typically, the brown pigmentation around the pupil spreads concentrically towards the periphery of the iris and the entire iris or parts of the iris become more brownish. Neither new nor freckles of the iris appear to be affected by treatment. While treatment with Brimonidine Ophthalmic Solution, 0.03% can be continued in patients who develop noticeably increased iris pigmentation, these patients should be examined regularly. See PATIENT COUNSELING INFORMATION, 17.1.	
5.2 Eyelash Changes Brimonidine Ophthalmic Solution, 0.03% may gradually change eyelashes and vellus hair in the treated eye. These changes include increased length, thickness and number of lashes. Eyelash changes are usually reversible upon discontinuation of treatment.	
5.3 Intraocular Inflammation Pseudoepitheliomatous keratitis, including Brimonidine, it has been reported to cause intraocular inflammation. In addition, because these products may exacerbate inflammation, caution should be used in patients with active intraocular inflammation (e.g., uveitis).	

