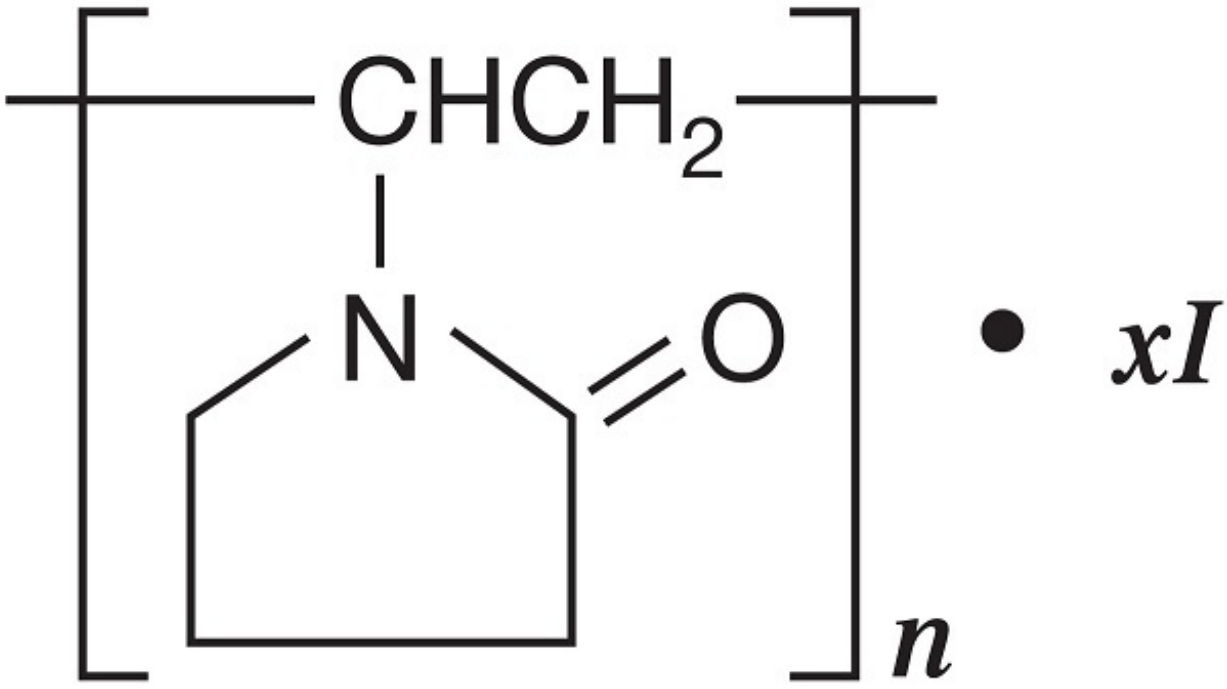
BETADINE- povidone-iodine solution
Alcon Laboratories, Inc.

BETADINE* 5% Sterile Ophthalmic Prep Solution (povidone-iodine ophthalmic solution) (0.5% available iodine)

DESCRIPTION

Povidone-Iodine is a broad-spectrum microbicide with the chemical formulas:

2-pyrrolidinone, 1- ethenyl-, homopolymer, compound with iodine; 1-vinyl-2-pyrrolidinone polymer, compound with iodine. The structural formula is as follows:



BETADINE* 5% Sterile Ophthalmic Prep Solution contains 5% povidone-iodine (0.5% available iodine) as a sterile dark brown solution stabilized by glycerin. **Inactive Ingredients:** purified water, citric acid, glycerin, nonoxynol-9, sodium chloride, sodium hydroxide, and dibasic sodium phosphate.

CLINICAL PHARMACOLOGY

A placebo-controlled study in 38 normal volunteers yielded data for 36 subjects who showed a mean $\log_{10}$ reduction of 3.05 $\log_{10}$ units in total aerobes at 10 minutes following prepping the skin with BETADINE* 5% Sterile Ophthalmic Prep Solution compared with reduction of 1.58 $\log_{10}$ units after prepping with vehicle free of the iodine complex. This placebo-controlled study indicates a mean $\log_{10}$ reduction by the iodine complex compared with the control solution of 1.47 $\log_{10}$ units at 10 minutes and 1.79 $\log_{10}$ units at 45 minutes. The base-line mean aerobic bacterial count was 7,586 organisms/cm^2.

INDICATIONS AND USAGE

BETADINE* 5% Sterile Ophthalmic Prep Solution for the eye is indicated for prepping of the

periocular region (lids, brow, and cheek) and irrigation of the ocular surface (cornea, conjunctiva, and palpebral fornices).

CONTRAINDICATIONS

Do not use on individuals known to be sensitive to iodine, or other components of this product.

WARNINGS

FOR EXTERNAL USE ONLY. NOT FOR INTRAOCULAR INJECTION OR IRRIGATION.

PRECAUTIONS

General

No studies are available in patients with thyroid disorders; therefore, caution is advised in using BETADINE* 5% Sterile Ophthalmic Prep Solution in these patients due to the possibility of iodine absorption.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long term studies in animals have been performed to evaluate the carcinogenic or mutagenic potential of povidone-iodine. One report of the mutagenic potential of povidone-iodine indicated that it was positive in a modification of the Ames S. **typhimurium** model, but these results could not be reproduced by another researcher. Another test using mouse lymphoma and Balb/3T3 cells showed that povidone-iodine has no significant mutagenic or transformation capabilities. Other data indicated that it does not produce mutagenic effects in mice or hamsters according to the dominant lethal test, micronucleus test, and chromosome analysis.

Pregnancy

Animal reproduction studies have not been conducted with BETADINE* 5% Sterile Ophthalmic Prep Solution. It is also not known whether BETADINE* 5% Sterile Ophthalmic Prep Solution can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. BETADINE* 5% Sterile Ophthalmic Prep Solution should only be used on a pregnant woman if clearly needed.

Nursing Mothers

Because of the potential for serious adverse reactions in nursing infants from BETADINE* 5% Sterile Ophthalmic Prep Solution, a decision should be made to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

No overall differences in safety or effectiveness have been observed between elderly and younger patients.

ADVERSE REACTIONS

Local sensitivity has been exhibited by some individuals to povidone-iodine ophthalmic solution.

DOSAGE AND ADMINISTRATION

While the inner surface and contents of the immediate container (i.e., bottle) are sterile, the outer surface of the bottle is not sterile. The use of the bottle in a sterile field should be avoided.

BETADINE* 5% Sterile Ophthalmic Prep Solution is used as follows:

1. Make sure container is intact before use. To open, COMPLETELY TWIST OFF TAB, do not pull off.
2. Gently pour entire contents of bottle into a sterile prep cup. Saturate sterile cotton-tipped applicator to prep lashes and lid margins using one or more applicators per lid; repeat once.
3. Saturate sterile prep sponge or other suitable material to prep lids, brow and cheek in a circular ever-expanding fashion until the entire field is covered; repeat prep three (3) times.
4. While separating the lids, irrigate the cornea, conjunctiva and palpebral fornices with BETADINE* 5% Sterile Ophthalmic Prep Solution using a sterile bulb syringe.
5. After the BETADINE* 5% Sterile Ophthalmic Prep Solution has been left in contact for two minutes, sterile saline solution in a bulb syringe should be used to flush the residual prep solution from the cornea, conjunctiva, and the palpebral fornices.

HOW SUPPLIED

BETADINE* 5% Sterile Ophthalmic Prep Solution is packaged under sterile conditions, and supplied in 1 fl oz (30 mL) form sealed blue HDPE bottles. Twenty-four (24) bottles are packed in each shipper.
NDC 0065-0411-30

Store at 15°C to 25°C (59°F-77°F).
Rx Only
Single-use only

Manufactured for:
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76134

Manufactured by:
Catalent Pharma Solutions, LLC
Woodstock, IL 60098

*BETADINE is a registered trademark of Purdue Products L.P.

Revised: June 2018
9008808

Principal Display Panel

NDC 0065-0411-30

Betadine* 5%
Sterile Ophthalmic Prep Solution
(povidone-iodine ophthalmic solution)

For Pre-Operative Prep and Irrigation of the Ocular and Periocular Surfaces

Flush eye thoroughly with sterile saline solution after each use.

Rx Only

1 Fl. Oz. (30 mL)

Alcon®
a Novartis company

Indications:
For prepping of the periocular region (lids, brow, and cheek) and irrigation of the ocular surface (cornea, conjunctiva, and palpebral fornices).

Contraindications:
Do not use on individuals known to be sensitive to iodine or other components of this product.

Warning:
For external use only.
NOT for intraocular injection or irrigation.

Read package insert for full use and directions and precautions.

Storage:
15°- 25°C (59°- 77°F).

Active Ingredient: povidone-iodine 5% (0.5% available iodine).

Inactive Ingredients: purified water, citric acid, dibasic sodium phosphate, glycerin, nonoxynol-9, sodium chloride, sodium hydroxide.

Single use only.

Manufactured for:
Alcon Laboratories, Inc.
Fort Worth, Texas 76134

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*BETADINE Reg. TM of Purdue Products L.P.

Alcon®
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Fort Worth, Texas 76134

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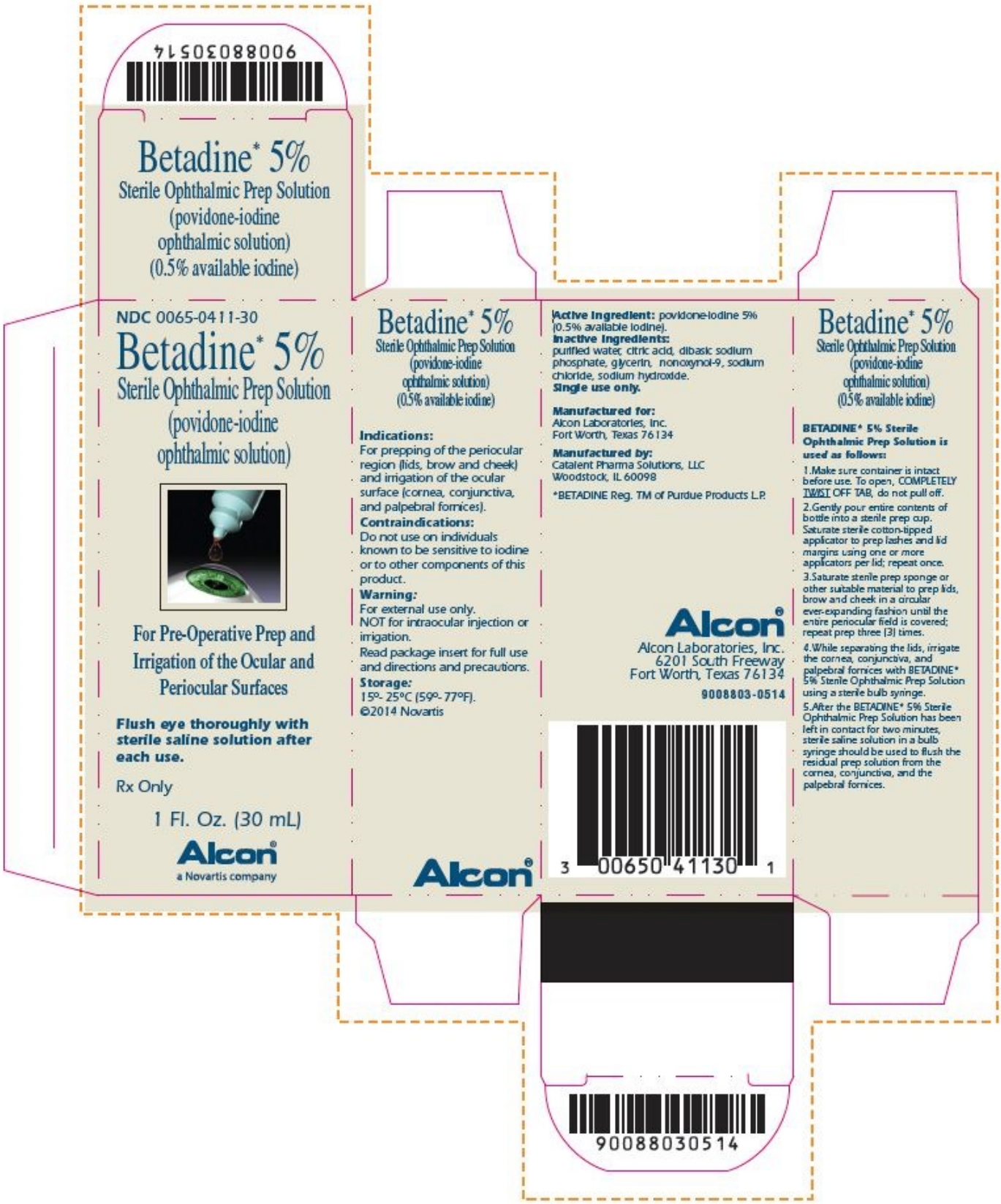


Rx only NDC 0065-0411-30

Betadine®

5% Sterile Ophthalmic Prep Solution
(povidone-iodine ophthalmic solution)

(0.5% available iodine)

1 fl. oz. (30mL)

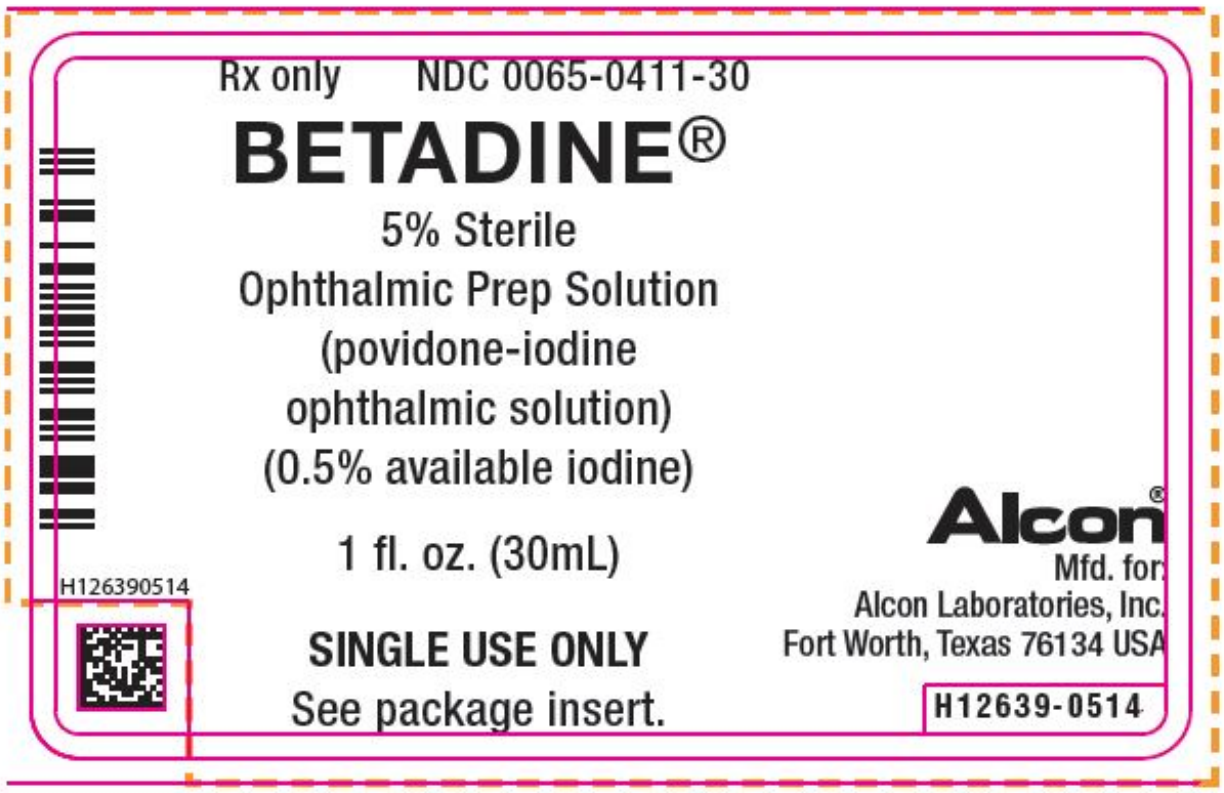
SINGLE USE ONLY

See package insert.

Alcon®

Mfd. for
Alcon Laboratories, Inc.
Fort Worth, Texas 76134 USA

H12639-0514



BETADINE
povidone-iodine solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0065-0411
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
NONOXYNOL-9 (UNII: 48Q180SH9T)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0065-0411-30	1 in 1 CARTON	04/01/2000	
1		30 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
NDA	NDA018634	04/01/2000	

Labeler - Alcon Laboratories, Inc. (008018525)

Registrant - Alcon Laboratories, Inc. (008018525)

Establishment

Name	Address	ID/FEI	Business Operations
Catalent Pharma Solutions, LLC		043911403	manufacture(0065-0411)

Revised: 7/2018 Alcon Laboratories, Inc.