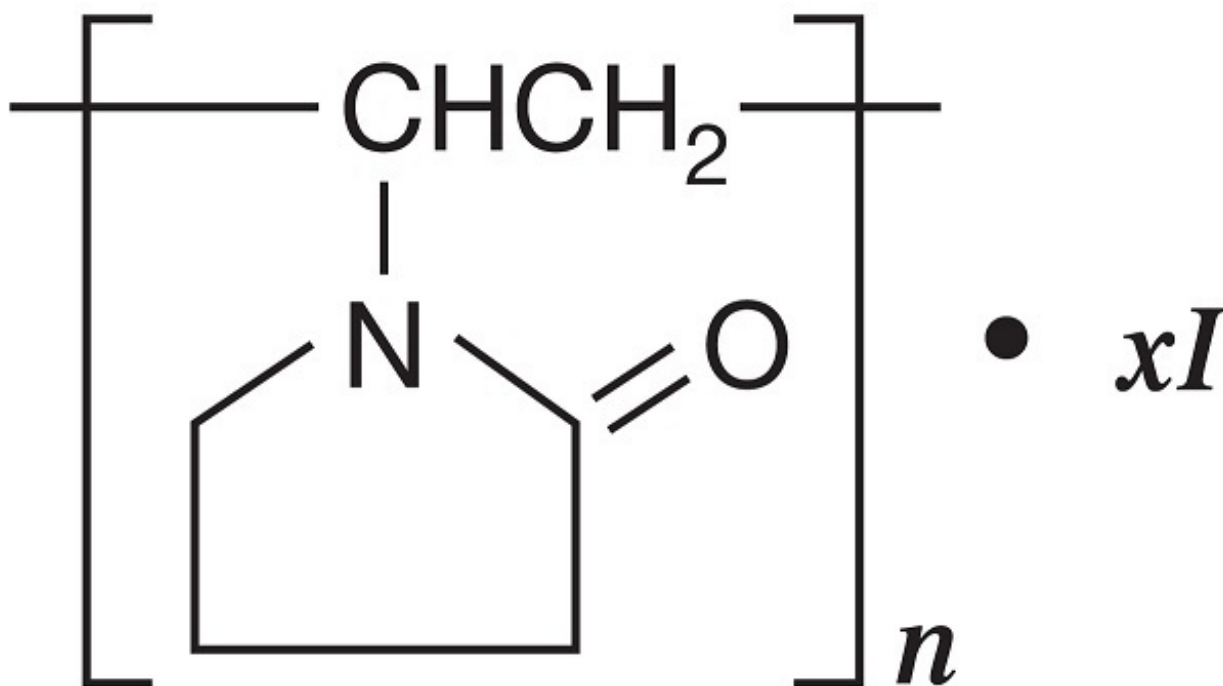


BETADINE- povidone-iodine solution
Alcon Laboratories, Inc.

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 log₁₀ reduction of 3.05 log₁₀ units in total aerobes at 10 minutes following prepping the skin with BETADINE* 5% Sterile Ophthalmic Prep Solution compared with reduction of 1.58 log₁₀ units after prepping with vehicle free of the iodine complex. This placebo-controlled study indicates a mean log₁₀ reduction by the iodine complex compared with the control solution of 1.47 log₁₀ units at 10 minutes and 1.79 log₁₀ units at 45 minutes. The base-line mean aerobic bacterial count was 7,586 organisms/cm².

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:

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

ALCON®

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.

WSTW-AC6024-642R00

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).

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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

Manufactured by:

Catalent Pharma Solutions, LLC
Woodstock, IL 60098

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

Alcon[®]

Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, Texas 76134

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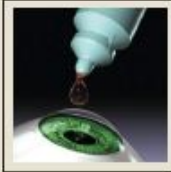
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Betadine* 5%
Sterile Ophthalmic Prep Solution
(povidone-iodine
ophthalmic solution)
(0.5% available iodine)

NDC 0065-0411-30

Betadine* 5%
Sterile Ophthalmic Prep Solution
(povidone-iodine
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known to be sensitive to iodine
or to 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).
©2014 Novartis

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

Inactive ingredients:

purified water, citric acid, dibasic sodium
phosphate, glycerin, nonoxonyl-9, sodium
chloride, sodium hydroxide.

Single use only.

Manufactured for:

Alcon Laboratories, Inc.
Fort Worth, Texas 76134

Manufactured by:

Catalent Pharma Solutions, LLC
Woodstock, IL 60098

*BETADINE Reg. TM of Purdue Products LP

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

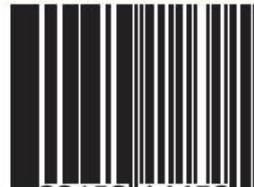
**BETADINE* 5% Sterile
Ophthalmic Prep Solution is
used as follows:**

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 periocular 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.

Alcon

Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, Texas 76134

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Alcon



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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

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

H126390514

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
Woodstock Sterile Solutions, Inc.		117895702	manufacture(0065-0411)

Revised: 5/2021

Alcon Laboratories, Inc.