EYE INJECTION KITS International, Inc. Organized for Sight™

- **MSDSCyclomydril**
- **Ofloxacin Ophthalmic Solution**
- **TetraVisc**
- **Betadine Ophthalmic**

Cyclomydril:

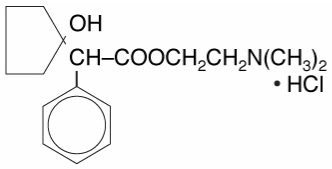
http://www.drugs.com/pro/cyclomydril.html

Generic Name: cyclopentolate hydrochloride and phenylephrine hydrochloride
Dosage Form: ophthalmic solution

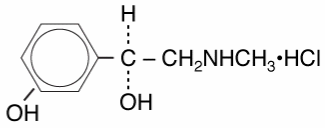
Cyclomydril®
(cyclopentolate hydrochloride and phenylephrine hydrochloride ophthalmic solution)
Sterile

DESCRIPTION

Cyclomydril® (cyclopentolate hydrochloride and phenylephrine hydrochloride ophthalmic solution) is a mydriatic prepared as a sterile topical ophthalmic solution. The active ingredients are represented by the chemical structures:



Established name:
Cyclopentolate Hydrochloride
Chemical name:
2-(Dimethylamino)ethyl 1-hydroxy-α-phenylcyclopentaneacetate hydrochloride



Established name:
Phenylephrine Hydrochloride
Chemical name:
3-hydroxy - α[(methylamino) -methyl]-, Benzenemethanol, hydrochloride (*R*)-.

Each mL contains: Active: cyclopentolate hydrochloride 0.2%, phenylephrine hydrochloride 1%. Preservative: benzalkonium chloride 0.01%. Inactives: edetate disodium, boric acid, hydrochloric acid and /or sodium carbonate (to adjust pH), purified water.

CLINICAL PHARMACOLOGY

Cyclopentolate hydrochloride is an anticholinergic drug and Phenylephrine hydrochloride is an adrenergic drug. This combination induces mydriasis that is greater than that of either drug alone at its respective concentration. The concentrations of cyclopentolate hydrochloride and phenylephrine hydrochloride have been selected to induce mydriasis with little accompanying cycloplegia. Heavily pigmented irides may require more doses than lightly pigmented irides.

INDICATIONS AND USAGE

For the production of mydriasis.

CONTRAINDICATIONS

Do not use in patients with untreated narrow-angle glaucoma or with untreated anatomically narrow angles or where there is hypersensitivity to any component of this preparation.

WARNINGS

FOR TOPICAL OPHTHALMIC USE ONLY. NOT FOR INJECTION. The use of this combination may have an adverse effect on individuals suffering from cardiovascular disease, hypertension, and hyperthyroidism, and it may cause CNS disturbances. Infants are especially prone to CNS and cardiopulmonary side effects from cyclopentolate. Observe infants closely for at least 30 minutes. Mydriatics may produce a transient elevation of intraocular pressure.

PRECAUTIONS

General

The lacrimal sac should be compressed by digital pressure for two to three minutes after instillation to reduce excessive systemic absorption. Caution should be observed when considering use of this medication in the presence of Down's syndrome and in those predisposed to angle-closure glaucoma. The effect of long-term use of this preparation has not been established, therefore, it should be restricted to short-term use.

Information for Patients

Do not touch dropper tip to any surface, as this may contaminate the solution. Patient should be advised not to drive or engage in hazardous activities while pupils are dilated. Patient may experience sensitivity to light and should protect eyes in bright illumination during dilation. Parents should be warned not to get this preparation in their child's mouth and to wash their own hands and the child's hands following administration. Feeding intolerance may follow ophthalmic use of this product in infants. It is recommended that feeding be withheld for four (4) hours after examination.

Drug Interactions

Cyclopentolate may interfere with the ocular anti-hypertensive action of carbachol, pilocarpine, or ophthalmic cholinesterase inhibitors.

Carcinogenesis, Mutagenesis, Impairment of Fertility

There have been no long-term studies done using cyclopentolate hydrochloride and/or phenylephrine hydrochloride in animals to evaluate carcinogenic potential.

Pregnancy

Pregnancy Category C. Animal reproduction studies have not been conducted with cyclopentolate hydrochloride and/or phenylephrine hydrochloride. It is also not known whether cyclopentolate hydrochloride and/or phenylephrine hydrochloride can cause

fetal harm when administered to a pregnant woman or can affect reproduction capacity. Cyclomydril® Ophthalmic Solution should be given to a pregnant woman only if clearly needed.

Nursing Mothers
It is not known whether these drugs are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Cyclomydril Ophthalmic Solution is administered to a nursing woman.

Pediatric Use
Use of cyclopentolate has been associated with psychotic reactions and behavioral disturbances in pediatric patients. Increased susceptibility to cyclopentolate has been reported in infants, young children, and in children with spastic paralysis or brain damage. These disturbances include ataxia, incoherent speech, restlessness, hallucinations, hyperactivity, seizures, disorientation as to time and place, and failure to recognize people. Feeding intolerance may follow ophthalmic use of this product in infants. It is recommended that feeding be withheld for four (4) hours after examination. Observe infants closely for at least 30 minutes.

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

ADVERSE REACTIONS
Ocular: The following ocular adverse experiences have been associated with the use of Cyclomydril: increased intraocular pressure, burning/irritation upon instillation, photophobia, blurred vision and superficial punctate keratitis.

Non-ocular: Use of cyclopentolate hydrochloride has been associated with psychotic reactions and behavioral disturbances in children. These disturbances include ataxia, incoherent speech, restlessness, hallucinations, hyperactivity, seizures, disorientation as to time and place, and failure to recognize people. This drug produces reactions similar to those of other adrenergic and anticholinergic drugs; however, the central nervous system manifestations as noted above are most common. Other manifestations of adrenergic and anticholinergic topical ophthalmic drugs include tachycardia, hyperpyrexia, hypertension, vasodilation, urinary retention, diminished gastrointestinal motility and decreased secretion in salivary and sweat glands, pharynx, bronchi and nasal passages. Severe manifestations of toxicity include coma, medullary paralysis and death.

OVERDOSAGE
Excessive dosage may produce behavioral disturbances, tachycardia, hyperpyrexia, hypertension, elevated intraocular pressure, vasodilation, urinary retention, diminished gastrointestinal motility and decreased secretion in salivary and sweat glands, pharynx,

bronchi and nasal passages. Patients exhibiting signs of overdosage should receive supportive care and monitoring.

DOSAGE AND ADMINISTRATION

Instill one drop in each eye every five to ten minutes. To minimize systemic absorption, apply pressure over the nasolacrimal sac for two to three minutes following instillation. Observe infants closely for at least 30 minutes.

Storage

Storage: Store at 8°- 27°C (46°- 80°F).

Rx Only
Revised: February 2004

249037-0204

Cyclomydril
cyclopentolate hydrochloride and phenylephrine hydrochloride solution/ drops

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	NDC Product Code (Source)	0065-0359
Route of Administration	OPHTHALMIC	DEA Schedule	

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
CYCLOPENTOLATE HYDROCHLORIDE (CYCLOPENTOLATE)	CYCLOPENTOLATE HYDROCHLORIDE	2 mg in 1 mL
PHENYLEPHRINE HYDROCHLORIDE (PHENYLEPHRINE)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
BENZALKONIUM CHLORIDE	
EDETATE DISODIUM	
BORIC ACID	
HYDROCHLORIC ACID	
SODIUM CARBONATE	
WATER	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

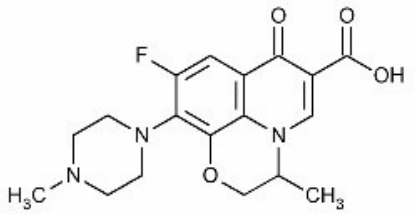
Ofloxacin Ophthalmic Solution

[http://www.drugs.com/pro/ofloxacin-ophthalmic-solution.html]

Dosage Form: ophthalmic solution
Ofloxacin Ophthalmic Solution USP

Ofloxacin Ophthalmic Solution Description

Ofloxacin Ophthalmic Solution USP, 0.3% is a sterile ophthalmic solution. It is a fluorinated carboxyquinolone anti-infective for topical ophthalmic use.
Chemical Name: (±)-9-Fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-7H-pyridol[1,2,3-de]-1,4 benzoxazine-6-carboxylic acid.



C18H20FN3O4Molecular Weight 361.37

Active: ofloxacin 0.3% (3 mg/mL).
Preservative: benzalkonium chloride (0.005%).

Inactives: sodium chloride and purified water. May also contain hydrochloric acid and/or sodium hydroxide to adjust pH.

Ofloxacin Ophthalmic Solution is unbuffered and formulated with a pH of 6.4 (range – 6.0 to 6.8). It has an osmolality of 300 mOsm/kg. Ofloxacin is a fluorinated 4-quinolone which differs from other fluorinated 4-quinolones in that there is a six member (pyridobenzoxazine) ring from positions 1 to 8 of the basic ring structure.

Ofloxacin Ophthalmic Solution - Clinical Pharmacology

Pharmacokinetics
Serum, urine and tear concentrations of ofloxacin were measured in 30 healthy women at various time points during a ten-day course of treatment with Ofloxacin Ophthalmic Solution. The mean serum ofloxacin concentration ranged from 0.4 ng/mL to 1.9 ng/mL. Maximum ofloxacin concentration increased from 1.1 ng/mL on day one to 1.9 ng/mL on day 11 after QID dosing for 10½ days. Maximum serum ofloxacin concentrations after ten days of topical ophthalmic dosing were more than 1000 times lower than those reported after standard oral doses of ofloxacin.
Tear ofloxacin concentrations ranged from 5.7 mcg/g to 31 mcg/g during the 40 minute period following the last dose on day 11. Mean tear concentration measured four hours after topical ophthalmic dosing was 9.2 mcg/g.

Corneal tissue concentrations of 4.4 mcg/mL were observed four hours after beginning topical ocular application of two drops of Ofloxacin Ophthalmic Solution every 30 minutes. Ofloxacin was excreted in the urine primarily unmodified.

Microbiology
Ofloxacin has in vitro activity against a broad range of gram-positive and gram-negative aerobic and anaerobic bacteria. Ofloxacin is bactericidal at concentrations equal to or slightly greater than inhibitory concentrations. Ofloxacin is thought to exert a bactericidal effect on susceptible bacterial cells by inhibiting DNA gyrase, an essential bacterial enzyme which is a critical catalyst in the duplication, transcription and repair of bacterial DNA.

Cross-resistance has been observed between ofloxacin and other fluoroquinolones. There is generally no cross-resistance between ofloxacin and other classes of antibacterial agents such as beta-lactams or aminoglycosides.

Ofloxacin has been shown to be active against most strains of the following organisms both in vitro and clinically, in conjunctival and/or corneal ulcer infections as described in the INDICATIONS AND USAGE section.

Aerobes, Gram-Positive:
Staphylococcus aureus
Staphylococcus epidermidis
Streptococcus pneumoniae

Anaerobic Species:
Propionibacterium acnes

Aerobes, Gram-Negative:
Enterobacter cloacae
Haemophilus influenzae
Proteus mirabilis
Pseudomonas aeruginosa
Serratia marcescens*
*Efficacy for this organism was studied in fewer than 10 infections

The safety and effectiveness of Ofloxacin Ophthalmic Solution in treating ophthalmologic infections due to the following organisms have not been established in adequate and well-controlled clinical trials. Ofloxacin Ophthalmic Solution has been shown to be active in vitro against most strains of these organisms but the clinical significance in ophthalmologic infections is unknown.

Aerobes, Gram-Positive:
Enterococcus faecalis
Listeria monocytogenes
Staphylococcus capitis

Staphylococcus hominus
Staphylococcus simulans
Streptococcus pyogenes

Aerobes, Gram-Negative:
Acinetobacter calcoaceticus var. anitratus
Acinetobacter calcoaceticus var. lwoffii
Citrobacter diversus
Citrobacter freundii
Enterobacter aerogenes
Enterobacter agglomerans
Escherichia coli
Haemophilus parainfluenzae
Klebsiella oxytoca
Klebsiella pneumoniae
Moraxella (Branhamella) catarrhalis
Moraxella lacunata
Morganella morganii
Neisseria gonorrhoeae
Pseudomonas acidovorans
Pseudomonas fluorescens
Shigella sonnei

Other:
Chlamydia trachomatis

Clinical Studies
Conjunctivitis: In a randomized, double-masked, multi-center clinical trial, Ofloxacin Ophthalmic Solution was superior to its vehicle after 2 days of treatment in patients with conjunctivitis and positive conjunctival cultures. Clinical outcomes for the trial demonstrated a clinical improvement rate of 86% (54/63) for the ofloxacin treated group versus 72% (48/67) for the placebo treated group after 2 days of therapy.

Microbiological outcomes for the same clinical trial demonstrated an eradication rate for causative pathogens of 65% (41/63) for the ofloxacin treated group versus 25% (17/67) for the vehicle treated group after 2 days of therapy. Please note that microbiologic eradication does not always correlate with clinical outcome in anti-infective trials.
Corneal Ulcers: In a randomized, double-masked, multi-center clinical trial of 140 subjects with positive cultures, Ofloxacin Ophthalmic Solution treated subjects had an overall clinical success rate (complete re-epithelialization and no progression of the infiltrate for two consecutive visits) of 82% (61/74) compared to 80% (53/66) for the fortified antibiotic group, consisting of 1.5% tobramycin and 10% cefazolin solutions. The median time to clinical success was 11 days for the ofloxacin treated group and 10 days for the fortified treatment group.

Indications and Usage for Ofloxacin Ophthalmic Solution

Ofloxacin Ophthalmic Solution is indicated for the treatment of infections caused by susceptible strains of the following bacteria in the conditions listed below:

Conjunctivitis
Gram-Positive Bacteria:
Staphylococcus aureus
Staphylococcus epidermidis
Streptococcus pneumoniae
Pseudomonas aeruginosa
Corneal Ulcers

Gram-Positive Bacteria:
Staphylococcus aureus
Staphylococcus epidermidis
Streptococcus pneumoniae

Gram-Negative Bacteria:
Enterobacter cloacae
Haemophilus influenzae
Proteus mirabilis

Gram-Negative Bacteria:
Pseudomonas aeruginosa
Serratia marcescens*
Anaerobic Species:
Propionibacterium acnes
*Efficacy for this organism was studied in fewer than 10 infection

ontraindications

Ofloxacin Ophthalmic Solution is contraindicated in patients with a history of hypersensitivity to ofloxacin, to other quinolones or to any of the components in this medication.

Warnings

NOT FOR INJECTION.
Ofloxacin Ophthalmic Solution should not be injected subconjunctivally, nor should it be introduced directly into the anterior chamber of the eye.

Serious and occasionally fatal hypersensitivity (anaphylactic) reactions, some following the first dose, have been reported in patients receiving systemic quinolones, including ofloxacin. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, angioedema (including laryngeal, pharyngeal or facial edema), airway obstruction, dyspnea, urticaria and itching. A rare occurrence of Stevens-Johnson syndrome, which progressed to toxic epidermal necrolysis, has been reported in a

patient who was receiving topical ophthalmic ofloxacin. If an allergic reaction of ofloxacin occurs, discontinue the drug. Serious acute hypersensitivity reactions may require immediate emergency treatment. Oxygen and airway management, including intubation should be administered as clinically indicated.

Precautions

General

As with other anti-infectives, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi. If superinfection occurs discontinue use and institute alternative therapy. Whenever clinical judgment dictates, the patient should be examined with the aid of magnification, such as slit lamp biomicroscopy and, where appropriate, fluorescein staining. Ofloxacin should be discontinued at the first appearance of a skin rash or any other sign of hypersensitivity reaction.

The systemic administration of quinolones, including ofloxacin, has led to lesions or erosions of the cartilage in weight-bearing joints and other signs of arthropathy in immature animals of various species. Ofloxacin, administered systemically at 10 mg/kg/day in young dogs (equivalent to 110 times the maximum recommended daily adult ophthalmic dose) has been associated with these types of effects.

Information for patients

Avoid contaminating the applicator tip with material from the eye, fingers or other source.

Systemic quinolones, including ofloxacin, have been associated with hypersensitivity reactions, even following a single dose. Discontinue use immediately and contact your physician at the first sign of a rash or allergic reaction.

Drug interactions

Specific drug interaction studies have not been conducted with Ofloxacin Ophthalmic Solution. However, the systemic administration of some quinolones has been shown to elevate plasma concentrations of theophylline, interfere with the metabolism of caffeine and enhance the effects of the oral anticoagulant warfarin and its derivatives and has been associated with transient elevations in serum creatinine in patients receiving cyclosporine concomitantly.

Carcinogenesis, mutagenesis, impairment of fertility

Long term studies to determine the carcinogenic potential of ofloxacin have not been conducted.

Ofloxacin was not mutagenic in the Ames test, in vitro and in vivo cytogenic assay, sister chromatid exchange assay (Chinese hamster and human cell lines), unscheduled DNA synthesis (UDS) assay using human fibroblasts, the dominant lethal assay or mouse micronucleus assay. Ofloxacin was positive in the UDS test using rat hepatocyte and in the mouse lymphoma assay.

In fertility studies in rats, ofloxacin did not affect male or female fertility or morphological or reproductive performance at oral dosing up to 360 mg/kg/day (equivalent to 4000 times the maximum recommended daily ophthalmic dose).

Pregnancy

Teratogenic effects

Pregnancy Category C: Ofloxacin has been shown to have an embryocidal effect in rats and in rabbits when given in doses of 810 mg/kg/day (equivalent to 9000 times the maximum recommended daily ophthalmic dose) and 160 mg/kg/day (equivalent to 1800 times the maximum recommended daily ophthalmic dose). These dosages resulted in decreased fetal body weight and increased fetal mortality in rats and rabbits, respectively. Minor fetal skeletal variations were reported in rats receiving doses of 810 mg/kg/day. Ofloxacin has not been shown to be teratogenic at doses as high as 810 mg/kg/day and 160 mg/kg/day when administered to pregnant rats and rabbits, respectively.

Nonteratogenic effects

Additional studies in rats with doses up to 360 mg/kg/day during late gestation showed no adverse effect on late fetal development, labor, delivery, lactation, neonatal viability or growth of the newborn.

There are, however, no adequate and well-controlled studies in pregnant women. Ofloxacin Ophthalmic Solution should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing mothers

In nursing women a single 200 mg oral dose resulted in concentrations of ofloxacin in milk which were similar to those found in plasma. It is not known whether ofloxacin is excreted in human milk following topical ophthalmic administration. Because of the potential for serious adverse reactions from ofloxacin in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric use

Safety and effectiveness in infants below the age of one year have not been established.

Quinolones, including ofloxacin, have been shown to cause arthropathy in immature animals after oral administration; however, topical ocular administration of ofloxacin to immature animals has not shown any arthropathy. There is no evidence that the ophthalmic dosage form of ofloxacin has any effect on weight bearing joints.

Geriatric use

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

Adverse Reactions

Ophthalmic Use

The most frequently reported drug-related adverse reaction was transient ocular burning or discomfort. Other reported reactions include stinging, redness, itching, chemical conjunctivitis/keratitis, ocular/periocular/facial edema, foreign body sensation, photophobia, blurred vision, tearing, dryness and eye pain. Rare reports of dizziness and nausea have been received.

Ofloxacin Ophthalmic Solution Dosage and Administration

The recommended dosage regimen for the treatment of bacterial conjunctivitis is:

Days 1 and 2	Instill one to two drops every two to four hours in the affected eye(s).
Days 3 through 7	Instill one to two drops four times daily.

The recommended dosage regimen for the treatment of bacterial cornealulcer is:

Days 1 and 2	Instill one to two drops into the affected eye every 30 minutes, while awake. Awaken at approximately four and six hours after retiring and instill one to two drops.
Days 3 through 7 to 9	Instill one to two drops hourly, while awake.
Days 7 to 9 through treatment completion	Instill one to two drops, four times daily.

Storage

Store at 20°to 25℃ (68°to 77℉)

OFLOXACIN OPHTHALMIC
ofloxacin ophthalmic solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	NDC Product Code (Source)	0185-7502
Route of Administration	AURICULAR (OTIC)	DEA Schedule	

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OFLOXACIN (OFLOXACIN)	OFLOXACIN	0.3 mL in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
HYDROCHLORIC ACID	
WATER	
SODIUM CHLORIDE	
SODIUM HYDROXIDE	

TetraVisc: NDA 54799-505

http://www.drugs.com/pro/tetravisc.html

Generic Name: tetracaine hydrochloride
Dosage Form: ophthalmic solution
TetraVisc Hydrochloride Ophthalmic Solution, USP 0.5% Viscous Sterile Rx Only

DESCRIPTON:

Tetracaine Hydrochloride 0.5% is a sterile topical ophthalmic solution useful in producing surface anesthesia of the eye. The
active ingredient is represented by the structural formula:

CH3(CH2)3NH COOCH2CH2N(CH3)2.HCl

CLINICAL PHARMACOLOGY:

Tetracaine Hydrochloride Ophthalmic Solution, USP 0.5% acts by decreasing the permeability of the neuronal membrane, thereby decreasing the flux of sodium, potassium and other ions associated with propagation of the nerve impulse. The onset of anesthesia usually begins within 30 seconds and lasts a relatively short period of time.

INDICATIONS AND USAGE:

For procedures in which a rapid and short acting topical ophthalmic anesthetic is indicated such as in tonometry, gonioscopy, removal of corneal foreign bodies, conjunctival scraping for diagnostic purposes, suture removal from the cornea or conjunctiva, other short corneal and conjunctival procedures.

Should not be used by the patient without physician supervision, or in those persons showing hypersensitivity to any component of this preparation. For topical ophthalmic use only. Not for parenteral use. Not for injection. Do not use solution if it contains crystals or if it is cloudy or discolored. Prolonged use results in diminished duration of anesthesia and retarded healing. This may cause the drug to be used more frequently, creating a "vicious circle". Subsequent corneal infection and/or corneal opacification with accompanying permanent visual loss or corneal perforation may occur. Prolonged use may also produce severe keratitis.

General:

Do not touch dropper tip to any surface as this may contaminate the solution. As with all anesthetics, continuous and prolonged use should be avoided. Protection of the eye from irritating chemicals, foreign bodies and rubbing during the period of anesthesia is very important. Tetracaine Hydrochloride Ophthalmic Solution, USP 0.5% should be used cautiously in patients with known allergy or cardiac disease. If signs of sensitivity develop during the treatment or irritation persists or increases, patients should be advised to discontinue use and consult prescribing physician.

Keep this and all drugs out of the reach of children . In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

After instillation of this product, the surface of the eye is insensitive and can be scratched without your feeling it. Do not rub eye. Do not instill this product repeatedly because severe eye damage may occur. No studies have been conducted in animals or in humans to evaluate the potential of these effects.

Pregnancy Category C:

Animal reproduction studies have not been performed with Tetracaine Hydrochloride. It is also not known whether Tetracaine Hydrochloride can cause fetal harm when administered to a pregnant woman or can affect reproduction. Tetracaine Hydrochloride Ophthalmic Solution, USP 0.5% should be given to pregnant women only if clearly needed. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be excercised when Tetracaine Hydrochloride Ophthalmic Solution, USP 0.5% is administered to a nursing woman.

Pediatric Use:

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS:

Transient symptoms (signs) such as stinging, burning, and conjunctival redness may occur. A rare, severe, immediate type allergic corneal reaction has been reported characterized by acute diffuse epithelial keratitis with filament formation and/or sloughing of large areas of necrotic epithelium, diffuse stromal edema, descemetitis and iritis. To report SUSPECTED ADVERSE REACTIONS, contact OCuSOFT, Inc. at (800) 233-5469 www.ocusoft.com.

DOSAGE AND ADMINISTRATION: Dosage:

One to two drops per eye.

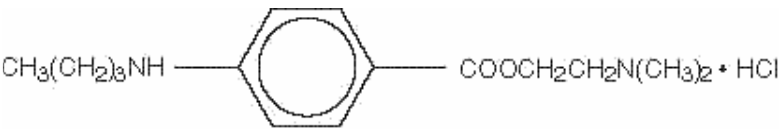
For Tonometry And Other Procedures Of Short Duration:
Instill one or two drops just prior to evaluation.

For Minor Surgical Procedures Such As Foreign Body Or Suture Removal:
Instill one or two drops in the eye(s) every five to ten minutes maximum three doses.

For Prolonged Anesthesia As In Cataract Extraction:
Instill one or two drops in the eye(s) every five to ten minutes maximum five doses.

Storage:

Store at a room temperature, 15°-30°C (59°-86°F).



TetraVisc
tetracaine hydrochloride liquid

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	NDC Product Code (Source)	54799-505
Route of Administration	OPHTHALMIC	DEA Schedule	

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Tetracaine Hydrochloride (Tetracaine)	Tetracaine Hydrochloride	25 mg in 5 mL

Inactive Ingredients	
Ingredient Name	Strength
Boric Acid	
Edetate Disodium	
Hypromelloses	
Potassium Chloride	
Sodium Borate	
Sodium Chloride	
Water	
Hydrochloric Acid	
Sodium Hydroxide	
BENZALKONIUM CHLORIDE	

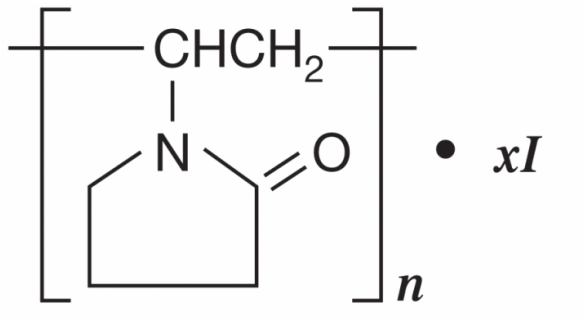
Betadine Ophthalmic:

http://www.drugs.com/pro/betadine-ophthalmic.html

Generic Name: povidone-iodine
Dosage Form: ophthalmic solution
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: 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 per square cm.

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
Category C: 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. Gently squeeze entire contents of bottle into a sterile prep cup.

2. 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.

Storage
Store at 15-25℃ (59-77℉).
Rx Only
Single use only
BETADINE® is a registered trademark of The Purdue Frederick Company.
9002984-1007

BETADINE
povidone-iodine solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	NDC Product Code (Source)	0065-0411
Route of Administration	OPHTHALMIC	DEA Schedule	

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (IODINE)	IODINE	5 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
CITRIC ACID MONOHYDRATE	
GLYCERIN	
NONOXYNOL-9	
SODIUM CHLORIDE	
SODIUM HYDROXIDE	
SODIUM PHOSPHATE, DIBASIC	