PRODUCT MONOGRAPH

OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution

POLYQUAD* (polyquaternium-1) 0.001%
Professed Standard

ALDOX* (myristamidopropyl dimethylamine) 0.0006%
Professed Standard

Contact Lens Disinfectant

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OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution

POLYQUAD* (polyquaternium-1) and ALDOX*
(myristamidopropyl dimethylamine)

PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Nonmedicinal Ingredients
Contact Lens Disinfectant	POLYQUAD* (polyquaternium-1) 0.001% and ALDOX* (myristamidopropyl dimethylamine) 0.0006% as disinfecting agents	None *For a complete listing see Dosage Forms, Composition and Packaging section.*

INDICATIONS AND CLINICAL USE

OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution (Multi-Purpose Disinfecting Solution) is indicated for:

- Use in the daily cleaning, reconditioning, rinsing, removing protein deposits, reducing lipid deposition, chemical (not heat) disinfection, and storage of silicone hydrogel and soft (hydrophilic) contact lenses, as recommended by your eye care professional.

Pediatrics (< 18 years of age):
No data are available.

CONTRAINDICATIONS

- OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution should not be used by patients who are hypersensitive to this product or to any ingredient in the formulation or component of the container. For a complete listing of ingredients, see the Dosage Forms, Composition and Packaging section of the product monograph.

WARNINGS AND PRECAUTIONS

General

Problems with contact lenses and lens care products could result in serious injury to the eye. It is essential that OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution users follow directions and all labeling instructions for proper use and care of their lenses and lens care products, including the lens case.

Eye problems, including infection and corneal ulcers, can develop rapidly and lead to loss of vision. OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution users should be advised to remove lenses immediately and contact their eye care practitioner promptly if they experience eye discomfort, excessive tearing, vision changes or redness of the eye. Daily-wear lenses are not indicated for overnight wear and should not be worn while sleeping. Clinical studies have shown the risk of serious adverse reactions is increased when these lenses are worn overnight. Extended-wear lenses should be removed regularly for cleaning and disinfection or for disposal and replacement on the schedule prescribed by eye care practitioner. Clinical studies have shown that there is an increased incidence of serious adverse reactions in extended-wear contact lens users as compared to daily-wear contact lens users. Studies have also shown that the risk of serious adverse reactions increases the longer extended-wear lenses are worn before removal for cleaning and disinfection or for disposal and replacement. Studies have also shown that smokers have a higher incidence of adverse reactions. Reuse of solution or use of water with lenses may lead to contamination resulting in eye injury and potential loss of vision. See below for additional important safety information.

OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution users should be instructed to:

- Always follow the product directions for use. Failure to follow product directions may lead to vision loss.
- Visit their eye care practitioner regularly.
- Always wash and dry hands before handling lenses.
- Not use tap water, bottled water or saliva with lenses or lens case.
- Always use fresh OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution. Never reuse the solution in the lens storage case.
- Avoid contamination, never touch dropper tip of the container to any surface.
- Replace cap after using.
- Keep the container tightly closed when not in use.
- Use before the expiration date marked on the product.
- Discard any remaining solution in their lens case after each disinfection cycle.
- Discard any remaining solution six months after first opening.
- Keep out of the reach of children.
- Not use with heat (thermal) disinfection.
- Not use saline or rewetting drops to disinfect lenses.
- Empty and rinse lens case with OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution and air-dry after use.

ADVERSE REACTIONS

Adverse Drug Reaction Overview

In general, the following problems may occur with use of contact lens solutions: eyes sting, burn or itch (irritation), comfort is less than when lens was first placed on the eye, feeling of something in the eye (foreign body, scratched area), excessive watering (tearing) of the eye, unusual eye secretions, redness of the eye, reduced sharpness of vision (poor visual acuity), blurred vision, rainbows or halos around objects, sensitivity to light (photophobia) or dry eyes. (See *Warnings and Precautions* Section*)*

Clinical Trial Adverse Drug Reactions

> *Because clinical trials are conducted under very specific conditions, the adverse reaction rates observed in the clinical trials may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse drug reaction information from clinical trials is useful for identifying drug-related adverse events and for approximating rates*.

During the clinical development of OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution, eight clinical trials were carried out (C-08-081, C-08-082, C-09-026, C-09-031, C-09-074, C-10-017, C-10-030, C-10-024). A total of 1093 subjects were exposed to the product. One hundred and thirteen (113) adverse events were reported of which 28 were related to use of the product, and of these 21were mild and the rest moderate. No adverse events were reported for the one-day clinical study (C-10-024). No adverse reactions were reported at an incidence greater than or equal to 1%.

Less Common Clinical Trial Adverse Drug Reactions (0.1-0.4%):

Eye disorders: keratitis, ocular discomfort, visual acuity reduced, conjunctival hyperaemia, ocular hyperaemia, conjunctivitis, eye allergy, eye irritation, eye pain, punctate keratitis.
General disorders and administration site conditions: eye complication associated with device (floppy contact lenses, dry contact lenses).
Immune system disorders: drug hypersensitivity.

Post-Market Adverse Drug Reactions

The most frequently reported spontaneous adverse events (all less than 1.04 per 100,000 units sold) consisted of burning sensation, discomfort, dry eye(s), irritation, and red eye(s). Other adverse events reported included blurred vision, conjunctivitis, corneal abrasion, corneal burn, corneal infiltrates, corneal scar, corneal ulcer, discharge, dizziness, edema, excessive blinking, excessive tearing, foreign body sensation, headache, hyperemia, hypersensitivity, impaired vision, infection, inflammation, itching, keratitis, nausea, pain, photophobia, reaction, skin irritation, and swelling.

INTERACTIONS

Overview

In vitro lens compatibility studies with OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution have shown that the lens care product is compatible with soft contact lenses from FDA Groups I, II and IV as well as silicone hydrogel lenses. Drug interaction studies with OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution and other ophthalmic solutions, *in vivo* or *in vitro*, have not been performed.

Not for use with heat (thermal) disinfection.

DOSAGE AND ADMINISTRATION

Recommended Dose and Dosage Adjustment

For use in the daily cleaning, reconditioning, rinsing, removing protein deposits, reducing lipid deposition, chemical (not heat) disinfection, and storage of silicone hydrogel and soft (hydrophilic) contact lenses.

- Thoroughly wet each side of the lens with OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution. Rub the lens for 20 seconds.
- Rinse each side of the lens for 10 seconds with a steady stream of OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution.
- Fill your lens case with fresh OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution. Store lenses in the closed lens case overnight or at least 6 hours. After soaking, lenses are ready to wear.
- Discard used solution from lens case after each use

If any debris remains on contact lenses, rinse with OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution prior to insertion. Lenses may be left in the unopened lens case containing OPTI-FREE* PureMoist* Multi-Purpose Disinfecting for up to 30 days. After this time, lenses must be cleaned and disinfected with OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution for 6 hours prior to wear.

OVERDOSAGE

Not applicable.

ACTION AND CLINICAL PHARMACOLOGY

Mechanism of Action

OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution contains dual disinfecting agents (POLYQUAD* (polyquaternium-1) and ALDOX* (myristamidopropyl dimethylamine) that reduces harmful microorganisms that can cause eye infections. It also contains a proprietary surfactant system (TETRONIC® 1304† and HydraGlyde* Moisture Matrix [EOBO - 41* - polyoxyethylene-polyoxybutylene]) that is designed for protein removal, reduction of lipid deposition; provides lens wettability and lubrication.

Benefits of OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution

OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution incorporates an established dual disinfection system with POLYQUAD* and ALDOX* as preservatives. OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution also combines the uses of the surfactant TETRONIC® 1304†, found in two marketed products (OPTI-FREE* Express* and OPTI-FREE* RepleniSH*), and EOBO, a new linear block copolymer surfactant composed of oxyethylene and oxybutylene units. The hydrophilic poly (oxyethylene) chain is long with a relatively high molecular weight and attracts water, whereas the poly (oxybutylene) chain is much shorter with a lower molecular weight and is attracted to hydrophobic lens sites.

EOBO was specifically designed to target silicone hydrogel lenses to provide lens cleaning, reduce lipid deposition, increase lens wettability and moisture, and provide cushioning and lens lubrication. A key surface chemistry property of the EOBO block copolymer is the ability to improve the wettability of soft lenses.

STORAGE AND STABILITY

OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution should be stored at room temperature (15-30°C). Lenses may be stored up to a maximum of 30 days in an unopened lens case. Lenses may be stored for longer but must be cleaned and disinfected with fresh OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution prior to lens insertion.

SPECIAL HANDLING INSTRUCTIONS

OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution users should be instructed to follow all eye care practitioner's directions and labeling instructions for proper use and care of lenses and lens care products, including the lens case. If they experience persistent eye discomfort, excessive tearing, vision changes, or redness of the eye, they should IMMEDIATELY remove their lenses and consult their eye care practitioner, as the problem could become more serious.

OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution users should be instructed to:

- Always follow the product directions for use. Failure to follow product directions

may lead to vision loss.
- Visit their eye care practitioner regularly.
- Always wash and dry hands before handling lenses.
- Not use tap water, bottled water or saliva with lenses or lens case.
- Always use fresh OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution. Never reuse the solution in the lens storage case.
- Avoid contamination, never touch dropper tip of the container to any surface.
- Replace cap after using.
- Keep the container tightly closed when not in use.
- Use before the expiration date marked on the product.
- Discard any remaining solution in their lens case after each disinfection cycle.
- Discard any remaining solution six months after first opening.
- Keep out of the reach of children.
- Not use with heat (thermal) disinfection.
- Not use saline or rewetting drops to disinfect lenses.
- Empty and rinse lens case with OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution and air-dry after use.

DOSAGE FORMS, COMPOSITION AND PACKAGING

OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution is a sterile, buffered, aqueous solution containing aminomethylpropanol, boric acid, disodium EDTA, sodium chloride, sodium citrate, sorbitol, two wetting agents (TETRONIC® 1304† and HydraGlyde* Moisture Matrix [EOBO - 41*- polyoxyethylene-polyoxybutylene]) with POLYQUAD* (polyquaternium-1) 0.001% and ALDOX* (myristamidopropyl dimethylamine) 0.0006% preservatives. Hydrochloric acid or sodium hydroxide is sometimes added to maintain proper pH balance (7.7 to 7.9). HydraGlyde* Moisture Matrix is a proprietary multi-functional block copolymer that is primarily designed for wetting and lubricating silicone hydrogel lenses.

OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution is available in sterile 60 mL, 120 mL, and 300 mL PET bottles. Bottles and cartons are marked with a lot number and expiration date.

†TETRONIC® is a registered trademark of BASF.

PART II: SCIENTIFIC INFORMATION

PHARMACEUTICAL INFORMATION

Drug Substance I & II

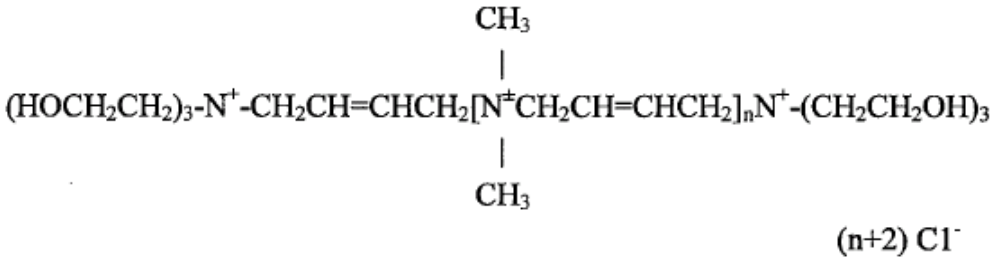
Drug Substance I

Proper name:
Polyquaternium-1 (POLYQUAD*)

Chemical name:
α-4-[1-tris (2-hydroxyethyl) ammonium chloride-2-butenyl] poly-[1-dimethyl ammonium chloride-2-butenyl]-ω-tris (2-hydroxylethyl) ammonium chloride.

Molecular formula and molecular mass:
$(C_6H_{12}ClN)_n \cdot C_{16}H_{36}Cl_2N_2O_6$
4600 – 11000 Daltons (based on acceptance criteria)

Structural Formula:



Physicochemical properties: Polyquaternium-1 (POLYQUAD*) is a clear, amber/brown, viscous liquid; freely soluble in water.

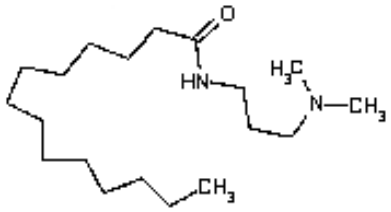
Drug Substance II

Proper name:
ALDOX*
Chemical name:
N-[3-(dimethylamino)propyl]tetradecamide

Molecular formula and molecular mass:
$C_{19}H_{40}N_2O$

312.54 M*r* (Relative Molecular Mass)

Structural Formula:



Physicochemical properties: ALDOX* N-[3-(dimethylamino)propyl]tetradecamide is a white to faintly yellow crystalline material that is slightly soluble in water, freely soluble in 2-propanol and dichloromethane.

CLINICAL TRIALS

Study demographics and trial design

Table 2: Summary of subject demographics for the clinical trials with OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution

Study	Trial Design	Dosage, Route of Administration and Duration	Study Subjects: Enrolled / Eligible / Completed	Mean Age (range)	Gender (M/F) (Eligible Study Subjects)
C-09-26	Randomized, parallel-group, concurrently controlled, double-masked, multi-site	Daily cycling[1] of S/H[2] and soft[3] contact lenses for 90 days.	573/569/544 561/561/535		159/402
		OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution (rub regimen)	288/285/274 282/282/270	33.7 (14-65)	72/210
		B+L® renu® fresh™ multi-purpose solution (rub regimen)	285/284/270 279/279/265	33.7 (13-71)	87/192
C-09-074	Randomized, parallel-group, concurrently controlled, double-masked, multi-site	Daily cycling[1] of S/H[2] contact lenses for 30 days.	591[4]/578/553		157/421
		OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution (rub regimen)	292/288/276	34.5 (18-65)	79/209
		B+L® renu® fresh™ multi-purpose solution (rub regimen)	297/290/277	34.0 (18-69)	78/212
C-08-082	Randomized, concurrently controlled, double-masked, single site, two-period crossover study	Daily cycling[1] of S/H[2] contact lenses for 7 day two-period crossover.	40/39[5]/40		17/23
		OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution (rub regimen)[6].	40/39/40	42.9 (26-61) OFP, RepleniSH sequence	8/12 OFP, RepleniSH sequence
		OPTI-FREE* RepleniSH* Multi-Purpose Disinfecting Solution[7]	40/39/40	42.4 (25-61) RepleniSH, OFP sequence	9/11 RepleniSH, OFP sequence

Study	Trial Design	Dosage, Route of Administration and Duration	Study Subjects: Enrolled / Eligible / Completed	Mean Age (range)	Gender (M/F) (Eligible Study Subjects)
C-10-017	Open label, non-randomized, multi-site	Daily cycling[1] of S/H[2] and soft[3] contact lenses for 30 days.			
		OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution (rub regimen)	175/171/171	37.5 (18-65)	63/108
C-10-024	Randomized, contralateral controlled, observer-masked, multi-site	One lens pre-soaked overnight and the other lens from blister pack. S/H[2] and soft[3] contact lenses worn for 1 day.			
		OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution	66/66/66	37.0 (18-62)	19/47
		Lens from blister pack			

[1]Cycling = Cleaning, rinsing, disinfection and storage.
[2]S/H = Silicone hydrogel contact lenses.
[3]Soft = Soft (hydrophilic) lenses (Groups I and IV).
[4]2 subjects were randomized to receive OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution, but did not receive test article due to having been randomized in error.
[5]Per Protocol dataset, OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution/RepleniSH® sequence.
[6]OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution/RepleniSH* sequence.
[7]RepleniSH*/OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution sequence.

Study results

Study C-09-026

The objective of study C-09-026 was to evaluate the safety and efficacy of OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution compared to renu® fresh™ Multi-Purpose Solution in silicone hydrogel and soft contact lens wearers. Subjects wore one of 6 different commercially available contact lens brands. In this ninety-day, randomized, parallel group, concurrently controlled, double-masked, multi-site study, both primary and secondary criteria were evaluated. During this study, eligible subjects wore lenses for approximately 8 hours or longer, with planned replacements (consistent with manufacturers' fitting guides), or when deemed necessary. Subjects were instructed to follow the lens care procedures appropriate for the assigned regimen up to and including storage.

Primary efficacy endpoints included corneal fluorescein staining (type and area), comfort, lens cleanliness, tarsal abnormalities, visual acuity, average lens wearing time, rewetting drop frequency and lens replacement incidence and causality.

The secondary efficacy variable was comfort at contact lens removal. Subjects reported lens comfort data via Interactive Voice Response System (IVRS) at both insertion and removal on each of the 10 days prior to the scheduled Day 90 visit (although, only the five days of data prior to the Day 90 visit were used in the analyses) by indicating their level of agreement to the Likert statement "My lens feel comfortable", within 5 minutes after inserting their lenses, and 5 minutes before removing their lenses. The response was based on a 5 point response scale: strongly agree, agree, undecided, disagree, and strongly disagree.

Subjects using OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution had significantly less corneal staining type ($p<0.0001$) and area ($p<0.05$) than subjects using renu® fresh™ Multi-Purpose Solution at Days 7, 30, 60 and 90 across lens brands.

OPTI-FREE® PureMoist™ Multi-Purpose Disinfecting Solution was effective in maintaining both ocular comfort and minimizing ocular symptoms. Most notably, OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution was deemed superior to renu® fresh™ Multi-Purpose Solution across all lens brands for comfort at 90 days (IVRS comfort diary), where 75% subjects agreed or strongly agreed to the statement that their lenses felt comfortable 5 minutes after insertion ($p<0.0001$) and 5 minutes before removal ($p=0.001$).

The mean values of responses to the following Likert statements "My lenses feel moist", "I can comfortably wear my lenses", "My lenses are comfortable all day", "At the end of the lens wearing day, my vision is clear", "The solution I use feels gentle in my eyes", "My lenses feel fresh", and "I like the way this product feels during handling" favoured OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution over renu® fresh™ Multi-Purpose Solution across all lens brands at Day 30, 60 and 90, and were statistically significant at a p-value of <0.05.

Lens cleanliness was measured by modified Rudko lens deposit classification and was also measured by mean percent areas of film and crystalline deposits. OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution was found to be effective in maintaining lens cleanliness, with similar percentages of subjects having both visibly and microscopically clean lenses as renu® fresh™ Multi-Purpose Solution.

Reduction of residual lens lysozyme on Group IV lenses favoured OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution with a p-value of <0.0001. Other primary criteria that showed substantial equivalence to renu® fresh™ Multi-Purpose Solution included the following: rewetting drop usage frequency, maintenance of healthy tarsal conjunctiva (slit-lamp findings), contact lens corrected visual acuity (Snellen) and average daily lens wearing time. There were fewer unscheduled lens replacements for subjects randomized to OPTI-FREE* PureMoist™ Multi-Purpose Disinfecting Solution ($p = 0.0264$) in comparison to those randomized to renu® fresh™ Multi-Purpose Solution with the most common reason for lens replacement in both regimens being damaged lenses.

Study C-09-074

This randomized, parallel group, concurrently controlled, double masked, 30 day multi- site study was designed to evaluate to OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution in comparison to renu® fresh™ Multi-Purpose Solution in symptomatic silicone hydrogel contact lens wearers, that is, subjects who had symptoms of discomfort when wearing contact lenses. Specifically, at baseline, the majority of C-09-074 subjects (76.3% and 73.4% in the OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution and renu® fresh™ Multi-Purpose Solution treatment groups, respectively) agreed or strongly agreed with the statement "During the day, I take my contacts out earlier than I like because they become uncomfortable". An even larger majority (86.1% and 91.0% in the OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution and renu® fresh™ Multi-Purpose Solution treatment groups, respectively) agreed or strongly agreed with the statement "Late in the day, my contacts become uncomfortable, but I continue wearing them".

Subjects used one of 4 different silicone hydrogel contact lens brands. The primary endpoint was for subject responses to the following Likert statement at Day 30: "When I use this solution, I can comfortably wear my lenses, while secondary endpoints were the additional statements: "When I use this solution, my lenses are comfortable from morning until evening" and "when I use this solution, I can comfortably wear my lenses". In this study, the subjects were instructed to wear their study lenses on a daily schedule, for at least 4 hours per day for the duration of the study. A two-week replacement schedule was followed, where one group of commercially available lenses were replaced after Day 14, while a second group of subjects wearing three other types of commercially available lenses were worn without planned replacement for the duration of the 30 day study.

For the primary efficacy variable, the mean difference for the Likert Statement, "When I use this solution, I can comfortably wear my lenses" at Day 30, was found to be statistically significant, with a p value of 0.0472. The difference in the means demonstrates the superiority of OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution in comparison to renu® fresh™ Multi-Purpose Solution across all lens brands combined.

Subjects using OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution reported a greater mean comfortable wear time (p=0.0411) than subjects using renu® fresh™ Multi-Purpose Solution, the mean difference observed from Day 0 to Day 30 in each treatment group being 1.8 hours for OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution versus 1.2 hours for renu® fresh™ Multi-Purpose Solution subjects**.**

The two co-secondary efficacy variables (Likert about 'comfort from morning until evening'(mean 3.3 vs 3.2, p = 0.4232) and lens wear such that I 'forget I am wearing my lenses') (means 3.2 vs 3.1, p = 0.2883) were intended to address factors of comfort duration and degree, respectively. Agreement to these statements can be considered supportive of a higher level of comfort than that presented by the primary variable. The fact that no differences were found between treatment groups for these statements may indicate that in this symptomatic contact lens population, the solution alone wasn't able to address all underlying issues of contact lens discomfort during daily wear. A number of supportive efficacy variables associated either

directly or indirectly with comfort did demonstrate differences in favor of OPTI-FREE® PureMoist™ Multi-Purpose Disinfecting Solution for all lens brands combined at Day 30, including longer comfortable lens wear time, reduced symptoms of scratchiness p=0.0243, burning p=0.0038, and stinging p=0.0150, as measured on a Visual Analog Scale (VAS). Additionally, OPTI-FREE demonstrated significantly reduced overall circumlimbal conjunctival staining (mean sum score p=0.0205). There were no statistically significant differences in the subject ratings for comfort (p=0.4341), dryness (p=0.7560), and irritation (p=0.4526).

There were no notable differences observed for all lens brands combined between OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution and renu® fresh™ MPS at Day 30 for supportive Likert statement responses, other VAS ratings, average lens wear time, rewetting drop frequency, *in-vivo* lens surface evaluations, ex-vivo lipid analysis, or contact lens corrected distance visual acuity change from baseline.

Study C-08-082

This study was a randomized, concurrently controlled, double-masked, single site, two-period crossover study in subjects with normal eyes designed to clinically evaluate the effect of OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution compared to OPTI-FREE* RepleniSH* Multi-Purpose Disinfecting Solution on wetting angles of two different silicone hydrogel lenses measured at 14 hours following 7 days of lens wear. Approximately 40 subjects (80 eyes) were asked to wear their lenses on a conventional, daily wear schedule (at least 8 hours a day) during each 7-day study period. The primary statistical objective of this study was to demonstrate that OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution is superior to OPTI-FREE* RepleniSH* Multi-Purpose Disinfecting Solution for ex-vivo wetting angles on silicone hydrogel lenses at the 14-hour time point following 7 days of lens wear, while secondary efficacy variables included questions to assess subjective comfort (acute (My lenses feel comfortable right now) and end of day frequency (How often have your lenses felt comfortable at the end of the day over the last 3 days?)), subjective discomfort (frequency (How often have your lenses felt uncomfortable over the last three days?)), solution-related corneal fluorescein staining, and corneal fluorescein staining (type and area).

The results show that there was no statistically significant difference between OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution and OPTI-FREE* RepleniSH* Multi-Purpose Disinfecting Solution for the primary endpoint of mean ex-vivo wetting angle, subject comfort questions (acute and end of day frequency), or for corneal staining area or type. There was, however, a statistically significant difference in favour of OPTI-FREE® PureMoist™ Multi-Purpose Disinfecting Solution for the subject discomfort question (frequency), overall (p=0.0141), as well as within the contact lens brand used by subjects (PureVision®, balafilcon A: p=0.0264). There was no solution-related corneal staining observed in either regimen, overall or by lens brand.

Study C-10-017

The primary statistical objective of this open label, 30 day, non-randomized, multi-site study in subjects with normal eyes was to describe mean differences in corneal staining (type and area), for OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution compared to baseline. At Baseline, Day 0, new contact lenses (subject's habitual brand) and test article were dispensed. Subjects were instructed to use the test article daily for care of their lenses according to the provided instructions and to return on Day 30 for assessments. OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution was also evaluated to describe product preference using a series of Likert statements such as "I prefer this solution to my previous solution", "My lenses are more comfortable with this solution compared to my previous solution", "I would continue to use this solution" based on the Day 30 assessment. Subjects were instructed to wear their study lenses on a daily wearing schedule [at least eight (8) hours per day] for the duration of the study. The manufacturer's recommended replacement schedule was followed during this 30-day study for all study lenses. Subjects wearing lenses that required a 2-week replacement replaced their study lenses outside of an office visit on Day 14 ± 1 day of the study. Subjects wearing monthly replacement lenses wore their study lenses daily wear without planned replacement for the full 30-day study duration. The primary efficacy outcome for this study was corneal staining (type and area). P-values from paired t-tests with a null hypothesis of no difference was provided as additional descriptors of the data (corneal staining type and area overall). The area (extent) of corneal staining for each of the five regions of the cornea was estimated [i.e., 0% (no staining in the region) to 100% (staining covers entire region)]. The study results showed a corneal staining type mean change from baseline to Day 30 of -0.82 ($p < 0.0001$) as well as a corneal staining area mean change from baseline to Day 30 of -5.04 ($p < 0.0001$). There was a mean change for comfortable wear time from baseline to Day 30 of 0.13 hours (approximately 8 minutes). A categorical change from baseline showed a 33.3% improvement ($p = 0.0106$) for subject agreement to the statement "When I use this solution, I can comfortably wear my lenses all day long". There was a categorical change from baseline demonstrating improvement of 42.7% ($p < 0.0001$) for subject agreement to the statement "When I use this solution, my lenses feel moist from insertion to removal". A categorical change from baseline showed an improvement of 42.1 % ($p < 0.0001$) for subjects agreeing to statement "When I use this solution, my lenses feel like new". Finally, a categorical change from baseline showed a 42.7% improvement ($p = 0.0002$) in subject agreement to the statement "When I use this solution, my lenses feel dry at the end of the day".

Study C-10-024

Wettability was assessed in a one-day, randomized, contralateral control, obsever-masked two-site study, C-10-024. The primary objective was to estimate the percentage of lenses that were rated wettable at the end of 16 (+1) hours of wear after pre-soaking in OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution overnight, and to estimate the percentage of lenses that were rated wettable at the end of 16(+1) hours after blister pack storage. The control article for the study is the blister pack contact lens storage solution. A total of 66 subjects (132 eyes, ~22 subjects per lens group) were enrolled. Volunteer subjects who successfully wore one of the commercially available study lens brands (one representative Group IV hydrogel lens and two others with hydrophobic/hydrophilic silicone hydrogel surface properties) on a daily wear schedule for at least 5 days prior to Visit 1 were recruited. Subjects who met the inclusion/exclusion criteria were dispensed new study lenses (a lens pre-soaked in OPTI-FREE*

PureMoist* Multi-Purpose Disinfecting Solution (OD) and a lens from the blister pack (OS); or a lens from the blister pack (OD) and a lens pre-soaked in OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution (OS)) at the conclusion of Visit 1 that matched their habitual lens brand in a randomized (1:1 ratio) at the conclusion of Visit 1. Subjects were instructed to insert the study lenses beginning the next morning and wear for 16 (+1) hours prior to Visit 2. At Visit 2, following 16 (+1) hours of wear, investigators rated the wettability of the lenses on eye using a 0-4 scale. Pre-lens non-invasive tear break-up time (PL-NITBUT) was assessed as well.

The study results demonstrated a 1.5% difference in wettability after 16(+1) hours of wear between lenses pre-soaked in OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution and lenses from blister pack storage ($p = 0.1718$) (based on mean values of 95.5% and 97.0%, respectively), and a 0.3 second difference in observed PL-NITBUT between the OPTI-FREE* PureMoist*™ Multi-Purpose Disinfecting Solution group and the blister pack group (based on mean values of 6.7 seconds and 6.4 seconds, respectively).

DETAILED PHARMACOLOGY

Disinfection Efficacy Testing

Stand-alone and regimen testing for disinfection efficacy testing were based on current ISO and ANSI standards and FDA guidelines Microorganisms used in these studies included gram-positive (*Staphylococcus aureus* ATCC 6538) and gram-negative (*Pseudomonas aeruginosa* ATCC 9027 and *Serratia marcescens* ATCC 13880) bacteria, yeast (*Candida albicans* ATCC 10231) and mold (*Fusarium solani* ATCC 36031). The stand-alone test method evaluates the antimicrobial activity of a product at pre-determined time intervals. In this study, samples of OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution were prepared with and without organic soil and evaluated for antimicrobial activity. Results indicated that the formulations met the primary criteria of the stand-alone test.

The regimen test method is used to establish instructions for cleaning (rubbing), rinsing and disinfecting (soaking) contact lenses. Four representative silicone hydrogel and 2 representative traditional soft (hydrophilic) contact lenses were challenged with each of the 5 representative microorganisms. The inoculated lenses were rubbed and then OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution was used to rinse and disinfect the lenses. Following the 6-hour disinfection time, the lenses and corresponding soaking solutions were evaluated for residual microorganisms. Results indicated that OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution meets the regimen test criteria for silicone hydrogel and traditional soft (hydrophilic) contact lenses.

Lens Cleaning

Cleaning effectiveness was assessed in a 90 day clinical study (C-09-026) that evaluated the safety and efficacy of OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution with traditional hydrogel lenses (and representative silicone hydrogel lenses). The control product was Bausch + Lomb™ renu® fresh™ Multi-Purpose Solution used according to the current label. Lens cleanliness was evaluated at each visit by clinical investigators using the modified Rudko lens deposit classification procedure. In addition, at the end of one 2-week lens replacement cycle,

(Group IV) lenses were collected and prepared for high performance liquid chromatography (HPLC) of residual lens lysozyme. The results demonstrated that OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution effectively cleans lenses. Lens cleanliness using the Rudko system was similar for the 2 regimens. OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution had less residual lens lysozyme as measured by HPLC compared to the control regimen at Day 30 (898 µg versus 1416 µg).

Comfort / Reconditioning
The results from the 90 day clinical study (C-09-026) demonstrated that subjects' lenses were comfortable from insertion to removal. Over 75% of subjects using OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution agreed with the statement "my lenses are comfortable" assessed in real-time using Interactive Voice Response System (IVRS) both at lens insertion and lens removal. In addition, the mean response to comfort at insertion and removal, favoured OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution over the control.

A clinical study (C-09-074) in contact lens patients with symptoms of discomfort showed differences favoring OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution for the primary Likert statement "I can comfortably wear my lenses" ($p = 0.047$) and for comfortable lens wear time ($p = 0.041$). Symptoms of ocular scratchiness, ocular burning, and ocular stinging were all rated lower after 30 days of use by subjects using OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution compared with those using renu® fresh™ Multi-Purpose Solution ($p \leq 0.024$).

Preservative efficacy
This testing was based upon ISO standard EN ISO 14730:2000. Microorganisms used in these studies included gram-positive (*Staphylococcus aureus* ATCC 6538) and gram-negative (*Pseudomonas aeruginosa* ATCC 9027 and *Escherichia coli* ATCC 8739) bacteria, yeast (*Candida albicans* ATCC 10231) and mold (*Aspergillus niger* ATCC 16404).

Stability lots of OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution were evaluated for preservative effectiveness through 28 days. Each lot was inoculated initially and again at day 14 (rechallenge) with each of 5 representative microorganisms. The inoculated samples were evaluated for viability at days 7, 14, 21 and 28. Results demonstrated that all stability lots met the EN ISO 14730 rechallenge preservative effectiveness test criteria through 28 days. In addition, samples of OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution prepared with 80% POLYQUAD*, 90% ALDOX* and 90% EDTA met the EN ISO 14730 PET criteria through 28 days.

The discard-date test, simulating long-term use of the product after the container has been opened, was conducted based upon the EN ISO 14730, Annex B. Results demonstrated that OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution meets the EN ISO 14730 Annex B criteria and maintains preservative effectiveness for 6 months after the container has been opened.

A separate simulated in-use test was conducted using stability lots stored at 25°C/40% RH and 30°C/65% RH for 108 weeks. Aliquots were dispensed from the bottles during the testing period

of 30 days. The residual product was evaluated for total viable microbial count using a bioburden assay based upon compendial methods. No viable microorganisms were detected in any of the bottles at the end of the in-use simulation period. Results indicated that the preservative system in OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution maintains the microbial quality of the product throughout the proposed in-use period.

A 30-day efficacy study of OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution was conducted, stored in the unopened lens case in the presence of contact lenses and organic soil. The study included challenges by 4 different organisms (*Pseudomonas aeruginosa, Serratia marcescens*, *Fusarium solani* and *Aspergillus niger*) to silicone hydrogel and traditional soft (hydrophilic) lenses with microbial evaluation of lenses and solution on 8 specified days. This study demonstrated microbial kill or inhibition by OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution over the 30-day test period.

16 hours Wettability

Wettability was assessed in a one-day, randomized, contralateral control, obsever-masked two-site study, C-10-024. Wettability after 16 hours of wear between lenses pre-soaked in OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution and lenses from blister pack storage was not significantly different.

Lens Compatibility

Lens compatibility was conducted with Groups I and IV traditional soft (hydrophilic) lenses and representative silicone hydrogel contact lenses in accordance with the current ISO standard [ISO 11981:2009].

In the study, the lens parameters measured were diameter, dioptric power, base curve, visible light transmittance and UV transmittance (for lenses containing UV blocker). Compatibility was determined by evaluating changes in physical and/or optical parameters after the completion of 30 cycles of a simulated-use regimen. During the study, minor changes to the lens diameter and base curve were observed in four of the silicone hydrogel lens brands. All changes were reversible in accordance with ISO 11981 guidelines. Based on these results, OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution is compatible with all traditional soft hydrophilic and silicone hydrogel contact lenses.

MICROBIOLOGY
Please refer to the **Detailed Pharmacology** section

TOXICOLOGY
A number of toxicity studies have been performed with OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution and packaging components including: ocular irritation, acute dose oral toxicity, sensitization, and cytotoxicity. All toxicology studies were conducted under GLP conditions according to FDA and international (ISO) standards.

The acute dose oral toxicity was evaluated in rats using a single 20mL/kg of body weight oral (gavage) dose of the undiluted OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution. All animals appeared normal throughout the study, and the gross necropsy examination revealed no test material-related lesions. It was concluded that OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution was not considered to be acutely toxic at a dose of 20 mL/kg by the oral route in the rat.

A single-dose ocular irritation study evaluated the potential of OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution to produce irritation following a single instillation to the ocular tissue of the rabbit. Ocular reactions were evaluated for 72 hours after the single exposure and revealed no ocular irritation. Similar single-dose ocular irritation studies were also performed as above using extracts of two commercial brands of soft contact lenses soaked in 100 mL of solution for 96 hours in OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution. OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution was formulated at the upper limit of the end-of-shelf-life product specification for biocides, and the lenses selected for study provided the highest level of biocide uptake and release. The purpose of these studies was to evaluate the potential for leachables extracted either with 0.9% sodium chloride or with sesame oil from the cycled lenses to produce irritation following a single instillation to the ocular tissue of the rabbit. It was found that the contact lenses tested did not produce any evidence of significant ocular irritation in the treated eyes as compared to the untreated control eyes.

In vivo ocular compatibility studies were performed on six commercial brands of contact lenses treated nightly with either OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution or a commercially available product. The purpose of these studies was to evaluate the potential for contact lenses maintained with the test solution to produce ocular irritation or toxicity in rabbits when used in the clinical regimen for up to 1 month. It was found that there were no ocular irritation trends that would be considered clinically significant, and microscopically the ocular tissue of the test and control eyes were similar and considered to be normal.

A delayed contact sensitization study was performed on OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution. The guinea pig maximization assay showed no sensitization response to the solution, and therefore, the solution is not considered a sensitizing agent.

In vitro cytotoxicity testing was conducted on OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution. An agar diffusion cytotoxicity study was conducted with undiluted OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution. There were no measurable zones of lysis around or under the treated filter paper discs, and it was concluded that OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution was not considered cytotoxic in this assay.

A modified elution assay tested OPTI-FREE* PureMoist* MPDS when diluted to 25% in cell culture medium. Only mild cytotoxicity was observed, and OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution was considered to be non-cytotoxic under the conditions of the test.

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PART III: CONSUMER INFORMATION

OPTI-FREE* PureMoist*
Multi-Purpose Disinfecting Solution
POLYQUAD* (polyquaternium-1) 0.001% and ALDOX*
(myristamidopropyl dimethylamine) 0.0006%

This leaflet is part III of a three-part "Product Monograph" published when OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution. Contact your eye care professional if you have any questions about the product.

ABOUT THIS PRODUCT

What the product is used for:
OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution is indicated for use in the daily conditioning, reconditioning, rinsing, removing protein deposits, reducing lipid deposition, chemical (not heat) disinfection, and storage of silicone hydrogel and soft (hydrophilic) contact lenses, as recommended by your eye care professional.

What it does:
When used as directed **OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution:**

- Cleans by removing protein deposits and reducing lipid deposition daily from your lenses during disinfection and storage.
- Uses biocompatible POLYQUAD* and ALDOX* dual disinfectants which have activity against harmful microorganisms (bacteria and fungi).
- Is used to rinse and recondition your silicone hydrogel and soft (hydrophilic) contact lenses.
- Is formulated to disinfect and store lenses for up to 30 days after disinfection.

Do not store your lenses in saline solution in place of **OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution.** Saline solution will not disinfect lenses.

When it should not be used:
If you are allergic to any ingredient in this product, do not use. (see "What the active ingredients are" and "What the other important ingredients are" sections.)

What the active ingredients are:
POLYQUAD* (polyquaternium-1) 0.001% and ALDOX* (myristamidopropyl dimethylamine) 0.0006% as disinfecting agents.

What the other important ingredients are:
OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution (Multi-Purpose Disinfecting Solution) is a sterile, buffered, aqueous solution containing aminomethylpropanol, boric acid, disodium EDTA, sodium chloride, sodium citrate, sorbitol, two wetting agents (TETRONIC®1304† and HydraGlyde* Moisture Matrix [EOBO-41*- polyoxyethylene-polyoxybutylene]). Hydrochloric acid or sodium hydroxide is sometimes added to maintain proper pH balance. HydraGlyde* Moisture Matrix is a proprietary multi-functional block copolymer that is primarily designed for wetting and lubricating silicone hydrogel lenses.

†TETRONIC® is a registered trademark of BASF.

What dosage forms it comes in:
OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution is available in sterile 60 mL, 120 mL, and 300 mL bottles. Bottles and cartons are marked with a lot number and expiration date.

WARNINGS AND PRECAUTIONS

IMPROPER USE OF CONTACT LENS AND LENS CARE PRODUCTS COULD RESULT IN CORNEAL INFECTION AND/OR ULCER AND LEAD TO LOSS OF VISION.

Problems with contact lenses and lens care products could result in serious injury to the eye. It is essential that you follow your eye care practitioner's directions and all labelling instructions for proper use and care of your lenses and lens care products, including the lens case. Eye problems, including infection and corneal ulcers can develop rapidly and lead to loss of vision. Daily-wear lenses are not indicated for overnight wear and should not be worn while sleeping. Clinical studies have shown the risk of serious adverse reactions is increased when these lenses are worn overnight. Extended-wear lenses should be removed regularly for cleaning and disinfection or for disposal and replacement on the schedule prescribed by your eye care practitioner. Clinical studies have shown that there is an increased incidence of serious adverse reactions in extended wear contact lens users as compared to daily wear contact lens users. Studies have also shown that the risk of serious adverse reactions increases the longer extended wear lenses are worn before removal for cleaning and disinfection or for disposal and replacement. Studies have also shown that smokers have a higher incidence of adverse reactions. If you experience eye discomfort, excessive tearing, vision changes, redness of the eye, immediately remove your lenses and promptly contact your eye care practitioner.
You should follow the complete recommended rubbing and rinsing times in the product labelling to adequately disinfect your lenses and reduce the risk of contact lens contamination. Reduced rubbing or rinsing time may not adequately clean your lenses.

Failure to discard solution from the lens case after each use or use of water to care for your lenses may lead to contamination

resulting in eye injury and potential loss of vision. See accompanying instructions for additional important safety information.

Important Safety Information:
Always follow the product directions for use. Failure to follow product directions may lead to vision loss.

- Visit your eye care practitioner regularly.
- Always wash and dry hands before handling lenses.
- Do not use tap water, bottled water or saliva with lenses or lens case.
- Always use fresh OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution. Never reuse the solution in the lens storage case.
- Avoid contamination, never touch dropper tip of the container to any surface.
- Replace cap after using.
- Keep the container tightly closed when not in use.
- Use before the expiration date marked on the product.
- Discard any remaining solution in your lens case after each disinfection cycle.
- Discard any remaining solution six months after first opening.
- Keep out of the reach of children.
- Do not use with heat (thermal) disinfection.
- Do not use saline or rewetting drops to disinfect lenses.
- Empty and rinse lens case with OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution and air-dry after use.

INTERACTIONS WITH THIS PRODUCT

No interactions are known, OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution is for use with silicone hydrogel and soft hydrophilic contact lenses.

Not for use with heat (thermal) disinfection.

PROPER USE OF THIS PRODUCT

For optimal results, follow these directions to clean, recondition, disinfect and remove protein:

- Thoroughly wet each side of the lens with **OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution**. Rub the lens for 20 seconds.
- Rinse each side of the lens for 10 seconds with a steady stream of **OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution.**
- Fill your lens case with fresh **OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution.** Store lenses in the closed lens case overnight or at least 6 hours. After soaking, lenses are ready to wear.

If any debris remains on contact lenses, rinse with **OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution** prior to insertion. You may leave your lenses in the unopened lens case containing **OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution** for up to 30 days. After this time, your lenses must be cleaned and disinfected for 6 hours with **OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution** prior to wear.

Always follow your eye care professional's instructions. Do not change your directions for care of your lenses or your care solution without consulting your eye care professional.

General Directions:

- Remove imprinted seal around bottleneck completely before use.
- Always wash, rinse and dry your hands thoroughly before you handle your lenses.
- Clean, recondition, rinse and disinfect your lenses each time you remove them.
- Always handle the same lens, the right or the left, first in order to avoid mix-ups.
- After use, always empty and rinse the lens case with fresh **OPTI-FREE* PureMoist* Multi-Purpose Disinfecting Solution** and allow to air dry.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

In general, the following problems may occur with use of contact lens solutions: eyes sting, burn or itch (irritation), comfort is less than when lens was first placed on the eye, feeling of something in the eye (foreign body, scratched area), excessive watering (tearing) of the eye, unusual eye secretions, redness of the eye, reduced sharpness of vision (poor visual acuity), blurred vision, rainbows or halos around objects, sensitivity to light (photophobia), or dry eyes.

If you notice any of the above:
Immediately remove your lenses.

- If the discomfort or problem stops, then look closely at the lens.
- If the lens is damaged in any way, DO NOT put the lens back on your eye. Place the lens in the storage case and contact your eye care practitioner.
- If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, thoroughly clean, recondition, rinse, and disinfect the lens, then reinsert it.
- If the problem continues, immediately remove the lens and consult your eye care practitioner.

If any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization or iritis may be present. Seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

This is not a complete list of side effects. For any unexpected effects while taking OPTI-FREE PureMoist* Multi-Purpose Disinfecting Solution, contact your eye care professional or pharmacist.*

HOW TO STORE IT

- Store solution at room temperature (15-30°C).
- Use before the expiration date marked on the carton and bottle.
- Discard any remaining solution 6 months after opening.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - **Fax toll-free to 1-866-678-6789, or**
  - **Mail to: Canada Vigilance Program**
    Health Canada
    Postal Locator 0701E
    Ottawa, Ontario
    K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:
http://www.alcon.ca
or by contacting the sponsor, Alcon Canada Inc., at:
1-800-613-2245.

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