



# OCuSOFT<sup>®</sup> ***HypoChlor***<sup>™</sup>

0.02% Hypochlorous Acid

# What Is OCuSOFT® HypoChlor™?

OCuSOFT® HypoChlor™ is a 0.02% concentration of Hypochlorous acid in both Spray and Gel formulation which can be used to supplement its existing OCuSOFT® Lid Scrub® family of eyelid cleansers in the most severe cases of eyelid disorders.



# What Is Hypochlorous Acid?

Hypochlorous acid is a weak acid that is formed when chlorine dissolves in water. Its chemical formula is HOCL. An acid is a pH below 7 (neutral). Above 7 is considered base/basic or alkaline. Tap water is generally a pH of 7 whereas citric acid from lemons is highly acidic at around a 2. The pH of HOCL is between 6-7.



# What Is Hypochlorous Acid (Cont.)?

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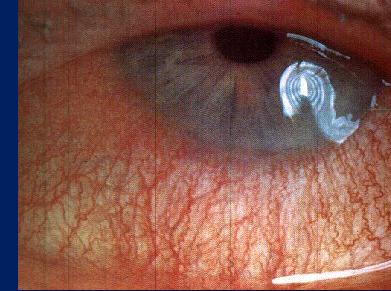
Hypochlorous acid is produced from either a chemical reaction or by electrolysis. Most HOCL solutions are made with Salt (NaCl) and Water (H<sub>2</sub>O) which are then electrolyzed to yield the chemical reaction HOCL (Hypochlorous acid) and OCl<sup>-</sup> (Hypochlorite ion or Sodium hypochlorite). Chlorine in water splits into two forms, Hypochlorous Acid (HOCl) and Hypochlorite Ion (OCl<sup>-</sup>). At the high pH the chlorine provided by bleach contains a maximum of Hypochlorite Ion. The chlorine produced by electrolysis contains a maximum concentration of Hypochlorous Acid (HOCl).

How much of each is present in a chlorine solution is totally dependent upon the pH of the solution. As pH rises, less Hypochlorous Acid and more Hypochlorite Ion is in the solution. As the pH rises, less germ killing power is available. According to a University of Illinois study, HOCl is 120 times more effective as a sanitizer than the OCl<sup>-</sup> ion. The ideal pH of a disinfecting chlorine solution is a pH of 6-7.

# When Is It Recommended?

As and adjunct to OCuSOFT® Lid Scrub® Eyelid Cleansers in the MOST SEVERE cases of eyelid conditions including:

- Dry Eye
- Meibomian Gland Dysfunction (MGD)
- Severe Blepharitis
- Demodex Infestation
- Pre-Operative Regimen



# What Are The Indications For Use?

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OCuSOFT® HypoChlor™ is intended for cleansing and removing foreign material and debris from the application site including microorganisms, immediate care of minor irritations to the skin, cleansing minor cuts, minor scrapes and minor burns. OCuSOFT® HypoChlor™ Gel provides a soothing, moist environment to expedite wound healing.

# Adjunctive Eyelid Relief

“In severe blepharitis cases, OCuSOFT® HypoChlor™ is a welcome addition; otherwise, OCuSOFT® Lid Scrub® PLUS with its anti-bacterial and surfactant properties is highly effective, and a mainstay of my eyelid hygiene treatment regimen.”

- Marguerite McDonald, MD, FACS



# What Is The Availability?

## ***Packaging Availability:***

- 2 Fl. Oz. (59 mL) Spray Pump Solution
- 2 Fl. Oz. (59 mL) Spray Pump Gel

## ***Location Availability:***

- Through a Dispensing Physician
- Online at [www.ocusoft.com](http://www.ocusoft.com)





# How Do I Use It?

Using a 100% cotton pad or cotton swab, spray gel onto the pad or swab until moistened. Use one pad or swab per eyelid. Close eyes and gently apply to eyelids and eyelashes using side to side motions. Use twice daily or as recommended.



# What Is The Cost?

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## ***Physician Cost:***

- 2 Fl. Oz. (59 mL) Spray Pump Solution - \$10.95
- 2 Fl. Oz. (59 mL) Spray Pump Gel - \$12.95
- Additional Discounts May Apply

## ***Patient Cost:***

- 2 Fl. Oz. (59 mL) Spray Pump Solution - \$21.95
- 2 Fl. Oz. (59 mL) Spray Pump Gel - \$25.95



# Who Is The Competition?



***Introducing Avenova\*.***

***For Daily Lid and  
Lash Hygiene.***

[Learn More](#)

***\*previously named NovaBay i-Lid™ Cleanser***

# What Is The Difference Between NovaBay's Avenova & OCuSOFT® HypoChlor™?

Avenova .01% HOCL is produced by acidification of sodium hypochlorite solution with hydrochloric acid to a pH of 3.5-4.5. NovaBay's marketing message of "pure" hypochlorous acid means that at this low pH, it doesn't contain sodium hypochlorite. Although at that low pH, it does contain several chlorinated species that are volatile and can only be maintained in the liquid phase equilibrium by having sealed, glass container. This sealed state is the 36 month shelf life that NovaBay markets, however, once the seal is broken and the container is open, the equilibrium rapidly shifts to the right with the loss of chlorinated species, the pH level rises, and the NovaBay product is only effective at killing bacteria for 30 days. This means it becomes nothing more than saline after 30 days of use.



# What Is The Difference Between NovaBay's Avenova & OCuSOFT® HypoChlor™ (Cont.)?

In contrast, OCuSOFT® HypoChlor™ is manufactured by electrolysis of water and salt to yield hypochlorous acid (.02%), sodium hypochlorite (.003%), and saline with a pH of 6-7. At this pH, the hypochlorous acid and sodium hypochlorite exist in balanced equilibrium with no volatile chlorine species to cause instability. As such, OCuSOFT® HypoChlor™ is effective and stable opened or unopened for 18 months. It is known that hypochlorous acid is more potent than sodium hypochlorite, as single species. However, equilibria of the two species at pH 6-7 would have significant concentrations of protonated acid (HOCl) to be potent and effective in its intended use.



# What Is The Difference Between NovaBay's Avenova & OCuSOFT® HypoChlor™ (Cont.)?

The stable pH (6-7) of OCuSOFT® HypoChlor™ allows for a gentler, robust and reliable product for application to eyelid tissue. It has been shown that 0.02% OCuSOFT® HypoChlor™ is non-irritating to ocular tissue (by Draize rabbit testing scored a perfect “0”). At pHs that are matched to physiological pH, OCuSOFT® HypoChlor™ has no irritation potential for the period of intended use as an eyelid scrub and cleanser or when instilled directly into the eye.



# Avenova Is A Prescription So It Must Be Better- Why Isn't HypoChlor™ A Prescription?

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The FDA requires Hypochlorous acid be registered as a medical device and as such may be marketed either as a prescription (Rx) or an Over-the-Counter (OTC) product based upon intended claims. Generally, the Rx vs. OTC designation has nothing to do with percentage of principle ingredient or relative effectiveness. It is simply a box that is checked on the 510-K that clarifies the labeling for the product. For example, OCuS OCuSOFT® HypoChlor™ Solution and OCuSOFT® HypoChlor™ Gel both contain 0.02% Hypochlorous acid and are being marketed as OTC products for use in the most severe conditions. Branded prescription products are more expensive than OTC products or generics when used in the same treatment category. OCuSOFT®'s 0.02% Hypochlorous acid is twice the strength of the competing prescription brand yet is marketed OTC in order to provide maximum patient savings and ease in purchasing the product without a prescription.



# Avenova Is A Prescription So It Must Be Better- Why Isn't HypoChlor™ A Prescription (Cont.)?

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If the doctor writes a prescription for Avenova, the patient can go to the pharmacy and get it filled, however, since it is a medical device, it won't be covered under any insurance, so they will pay an out-of-pocket expense of around \$30. If the doctor writes a prescription for OCuSOFT® HypoChlor™, the same steps apply, only the cost to the patient will be around \$20-25 for a 2 oz. bottle that will be stable for 18 months opened or unopened.



# What is a Surfactant?

A surfactant is the most important part of any cleaning agent. The word surfactant is short for “Surface Active Agent.” In general, they are chemicals that, when dissolved in water or another solvent, orient themselves at the interface (boundary) between the liquid and a solid (the dirt we are removing), and modify the properties of the interface.



# How Does a Surfactant Work?

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All have a common molecular similarity. One end of the molecule has a long nonpolar chain that is attracted to oil, grease, and dirt (the hydrophobe). Another part of the molecule is attracted to water (the hydrophile). The surfactant lines up at the interface. The hydrophobic end of the molecule gets away from the water and the hydrophilic end stays next to the water. When dirt or grease is present (hydrophobic in nature) the surfactants surround it until it is dislodged from the boundary. The dirt, oil, or grease is actually suspended in solution.

# NovaBay Claims That Surfactants Are Harmful To The Eyelid Margin & The Ocular Surface

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**NovaBay has NO SURFACTANTS.** The root cause of anterior blepharitis is the overproduction of oils. Mild surfactants in OCuSOFT® Lid Scrub® eyelid cleansers act to dissolve and remove oil, debris and desquamated skin. Hypochlorous acid formulas do not contain these surfactants and thus are largely ineffective in debriding the oil, scales and debris often associated with eyelid irritations. Since OCuSOFT® Lid Scrub® PLUS contains anti-bacterial properties, in cases of bacterial blepharitis treatment, this ONE product will effectively treat most patients. Only in the most severe cases of blepharitis is where Hypochlorous acid might be most beneficial, we suggest to use Combination Therapy including both a surfactant cleanser and Hypochlorous acid to achieve optimum results.

# NovaBay Claims That Surfactants Are Harmful To The Eyelid Margin & The Ocular Surface (Cont.)

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Since the indication for Hypochlorous acid products has been in wound care, it is interesting to note that debridement claims made by Hypochlorous acid products are due to the spray projectile packaging of all Hypochlorous acid products rather than strength of the concentration. Significantly, none of the Hypochlorous acid formulations on the market contain any surfactants to remove oil from the eyelids. Most expert ophthalmologists and optometrists agree that the surfactant components of existing eyelid cleansers are necessary to remove excessive oil, debris and desquamated skin from the eyelids. In the article, “Alternative Products Available to Combat Ocular Surface Disease” that ran in the November 2014 issue of Primary Care Optometry News, Katherine Mastrotta, O.D., recommends pairing a Hypochlorous acid product with a “doctor recommended surfactant product.”

# What Is The Shelf-Life & Stability?

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The shelf-life of NovaBay's Avenova is 3 years, however, once the product is opened, its equilibrium shifts, chlorine gas is released and it degrades into saline after 30 days. Therefore, one bottle of Avenova only lasts one month. Compare this to OCuSOFT® HypoChlor™ that has an 18 month shelf-life and stability either opened or unopened. Since we believe that OCuSOFT® HypoChlor™ should only be used as an adjunct to eyelid cleansers and for severe cases only, OCuSOFT® HypoChlor™ 's 2oz. bottle could last a patient for 3-6 months. Once the eyelid irritation is under control within the first 2 weeks of treatment with OCuSOFT® Lid Scrub® Plus and OCuSOFT® HypoChlor™ , then the patient can switch to a low cost maintenance regimen of OCuSOFT® Lid Scrub® Original.

# What Is The True Cost Difference To The Patient?

A minimum order of Avenova on-line through NovaBay's website is 3 bottles at \$30 each in 1.33 oz. Annual treatment with Avenova would cost at least \$360. Compare this with the recommended therapy of OCuSOFT® HypoChlor™ (\$21.95), OCuSOFT® Lid Scrub® PLUS (\$20) for the first two weeks of treatment, then OCuSOFT® Lid Scrub® Original monthly thereafter (\$20 for a 90 day supply 7.25 oz. bottle) equals \$121.00 per year. This is a savings to the patient of 66% using the OCuSOFT® preferred therapy.



# What About Use For Styes Or Chalazions in Pediatric Ophthalmology?

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In the last few weeks we have come across some Pediatric Ophthalmologists who are utilizing Avenova. After probing, they said they are using the product on their patients with recurring styes and chalazions. A stye or hordeolum, is an inflammation of part of the eyelid caused by an infection in the oil-producing sebaceous or sweat glands in the eyelid. Occurrence is greater in children than adults. As chalazion is a persistent inflammation or swelling of the upper or lower eyelid that can also include the middle part of the eyelid. Swelling may also occur in other parts of the eye due to a secondary infection. A chalazion is caused by a blockage of one of the meibomian glands in the eyelid which results in a cyst. Swelling associated with a chalazion is not usually painful, but the entire lid may become swollen and painful if the initial chalazion becomes infected. A small chalazion may go away on its own without treatment in a couple of months.

# What About Use For Stytes Or Chalazions in Pediatric Ophthalmology (Cont.)?

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While we are all focused on growing sales in our territories, we also need to be focused on ensuring Avenova does not gain traction. Please be on alert when in pediatric ophthalmology practices or in group practices that contain a pediatric ophthalmologist that they may be using or considering using a hypochlorous acid product for these patients.

So we are clear, please don't start promoting OCuSOFT® HypoChlor™ as a "cure" for stytes and chalazions. Simply make your doctors aware that it is a treatment which some other doctors are experimenting with and the antibacterial impact of HypoChlor could be a valuable tool in the treatment of recurring stytes and chalazions.



# In Summary

Doctors have long treated blepharitis and lid disease by recommending mild cleansers with surfactants (baby shampoo initially, then commercial lid cleansers such as OCuSOFT® Lid Scrub®) and prescribing antibiotics when necessary. Although most antibiotic prescriptions will kill the primary bacterial flora found on the eyelid, a surfactant cleanser was, and still is, recommended first to debride the eyelid and remove excessive oil that harbor bacteria.

