The Moisture Seekers

Sjögren's Syndrome Foundation

www.sjogrens.org

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# Blepharitis and the Sjögren's Patient

*by Gary N. Foulks, MD, Arthur and Virginia Keeney,Professor of Ophthalmology, University of Louisville, Louisville, KY*

Blepharitis, one of the most common problems seen by eye care specialists, may affect as many as 30 million Americans.[1] Its prevalence increases with age, though eye care specialists are seeing it more in younger patients. Most significantly, this condition appears to be more prevalent in Sjögren's syndrome patients.[2,3]

If left untreated, blepharitis can impact a patient's eye health, appearance, contact lens use, and quality of life. Unchecked blepharitis can compromise results of cataract or LASIK surgery.

## What is Blepharitis?

Blepharitis involves inflammation of the eyelid.[4] It can be caused by a variety of factors (e.g., age, allergy, immune system problems, hormone changes, bacteria, and dermatitis).

Symptoms can range from irritation and redness of the eyelid margin to problems with reading, using a computer, or watching television. It is more common to see blepharitis as lid margin disease. This condition can affect the front (anterior) or the back (posterior) of the eyelid. Many patients experience both forms (Figure 1).

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# The SSF Announces 2010 Research Grant Recipients – Donations Made the Difference!

*by Katherine Hammitt, SSF Vice President of Research, and Cynthia Williamson, SSF Research Associate*

We are experiencing a distressing dichotomy in research with more scientific opportunities in Sjögren's than ever before that are ripe for research, and yet, with tough economic times experienced in the U.S. and throughout the world, the future of medical and scientific research is uncertain. The National Institutes of Health, the federal agency and largest dispenser of research funds in the world, reports that the percentage of research grant applications that are funded by the NIH has dropped from 40% to 20% over the last 30 years. At the same time, the National Health Council reports that 37% of non-profits surveyed this year say they were cutting funds for research.

"We are very fortunate that the Sjögren's

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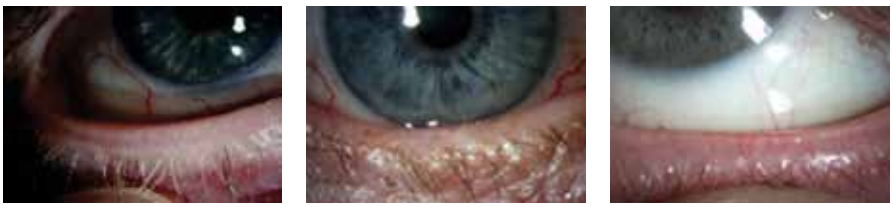
## In This Issue

*"Blepharitis" continued from page 1 ▼*

*Table 1: Comparison of Anterior and Posterior Blepharitis*

| | Anterior | Posterior |
|---|---|---|
| Etiology | Bacteria<br>Dermatitis | MGD, Aging, Sjögren's<br>Hormone changes<br>Immunologic effects |
| Presentation | Irritation<br>Crusty eyes<br>Collarette<br>Inflammation/redness | Vision problems<br>Dry eye |
| Sjögren's | Not necessarily | Definite link |
| Treatment | Lid hygiene<br>Doxycycline (oral)<br>Azithromycin (topical)<br>(Azasite®)<br>Antibiotic/Steroid<br>(TobraDex® ST Suspension | Lid hygiene<br>Lid massage<br>Lipid containing artificial tears<br>(Systane® Balance Lubricant Tears)<br>Doxycycline (oral)<br>Azithromycin (topical)<br>(Azasite®)<br>Cyclosporin (in moderate-to-severe cases)<br>(Restasis®) |

*Figure 1: Overlap of Anterior / Posterior Blepharitis (Courtesy K. Nichols, OD, PhD)*



*Anterior* *Mixed* *Posterior*

*Figure 2: Collarettes*

Anterior blepharitis is caused by an imbalance of bacteria normally found on the lid. The most common involve the Staphyloccus family (e.g., S. epididimis and S. aureus). These bacteria release toxins which can cause eyelid inflammation, redness, irritation, crustiness, eyelash debris or collarettes (Figure 2), and eyelash loss.

Posterior blepharitis involves the inside or back portion of the lid margin. A problem with sebaceous glands known as meibomian gland dysfunction (MGD) is the most common cause. MGD is more common in patients with rosacea. Factors that can contribute to MGD include advancing age and hormone changes. In patients with MGD, the meibomian gland secretions contain an abnormal or absent lipid. This abnormality destabilizes the tear film and can lead to evaporative dry eye, the most common type of dry eye. While MGD can initially appear without inflammation, it will often progress to a more inflamed condition.

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### Why is blepharitis relevant to patients with Sjögren's?

A study conducted in Japan found that patients with Sjögren's syndrome are at increased risk of getting blepharitis, particularly posterior disease or MGD.[2,3] As Sjögren's is more common in women than in men, blepharitis is most likely due to changes in androgen and estrogen balance following menopause. Immunologic changes may also play a role. Together these factors alter the meibomian gland.

Blepharitis can be problematic in Sjögren's patients, causing irritation and evaporative dry eye. In the past, it was generally thought that Sjögren's patients had dry eye primarily due to aqueous deficiency. If patients do not have enough tears, the higher rate of evaporation produces symptoms earlier. Likewise, if patients have evaporative dry eye and cannot make enough tears, they will have aggravated symptoms.

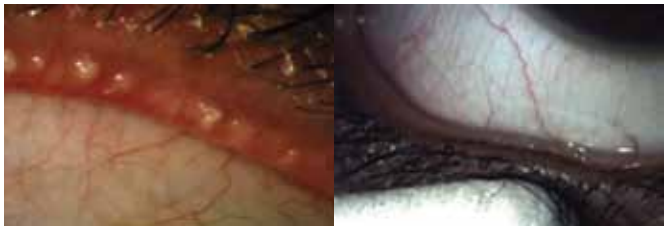
### What does your eye care doctor look for?

The classic symptom of anterior blepharitis is irritation of the eyelid. Patients also commonly experience crusting, accumulation of debris on the eyelashes, and redness at the base of the eyelashes.

Posterior blepharitis can be more subtle. Patients may not notice any irritations or inflammation in the eyelid, but they often complain of difficulties associated with reading, using a computer, or watching television.

During an exam, the eye specialist usually looks at the patient's eyes through a slit lamp, a microscope-like instrument, to view the eye in more detail. In patients with MGD, the doctor will see plugged glands and thickened secretions (Figure 3). The doctor also will see very rapid tear film breakup (5 seconds or less), a prominent sign of MGD.

*Figure 3: Plugged Meibomian Glands/ Expression of Meibomian Glands*



The doctor often will press on the eyelid to "express" the secretions to determine if the glands are producing lipid, and see what it looks like. The doctor notes how easily the secretion comes out, and if the secretion is cloudy, with debris, and is thick, like toothpaste, in advanced cases.

### What is available for Sjögren's with blepharitis?

Lid hygiene is a cornerstone in controlling anterior and posterior blepharitis. Patients should use a cotton ball or lid scrub to remove crusts from the eyelashes every day. MGD patients should apply hot compresses to help melt secretions from the glands, and then gently massage the lid with their fingertips to express the secretions.

With anterior blepharitis, treating the underlying bacterial problem and controlling inflammation are crucial. Treatment is directed at the base of the eyelashes, using an antibiotic such as topical erythromycin or topical azithromycin (AZASITE®) or an antibiotic with an anti-inflammatory, such as TOBRADEX® Suspension and TOBRADEX® ST Suspension (sidebar).

In posterior blepharitis, bacteria secrete enzymes and toxins that can contribute to inflammation. Antibiotics may be used here, typically topical azithromycin or oral doxycycline.

Artificial tear therapy is an important part of managing MGD and posterior blepharitis due to the associated tear instability and evaporative dry eye. The ideal tear should contain a component to thicken the tear film lipid layer and another to reduce evaporation. SOOTHE® and FRESHKOTE® are examples of such products.

This fall, SYSTANE® Balance Lubricant Eye Drops was released to the market for dry eye patients with MGD. My experience from two small clinical studies involving Sjögren's and MGD patients is that these drops are well-tolerated and preferred by most patients to their previous lubricants. With more experience emerging with this product, I find myself using it more as a tear-stabilizing agent.

For patients with more moderate-to-severe disease not responding to initial treatments, topical cyclosporine (RESTASIS®) is an additional option.

### Should I discuss with my eye care doctor regarding blepharitis?

Sjögren's patients need to tell their eye doctor about any problems they have with reading, using a computer, or watching television. They should also let the doctor know about any eyelid crusting or redness.

As the discussion should involve a two-way conversation, patients should ask their doctors a few key questions:

- *Do you see any evidence of MGD?*
- *Does my tear film appear stable? Would it be appropriate for me to use a lipid enhanced artificial tear such as SYSTANE® Balance Lubricant Eye Drops?*
- *Am I a candidate for an antibiotic like oral doxycycline or topical azithromycin or a combination like TOBRADEX® ST Suspension?*

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"Blepharitis" continued from page 3 ▼

## The bottom line

Sjögren's syndrome predisposes patients to posterior blepharitis and MGD. Patients need to be alert for problems in vision, irritation, redness, or crusty eyelids. Communication with your eye doctor can help him or her to examine your eyes in more detail and recommend appropriate treatment such as some of the newer options.

Knowledge about blepharitis and MGD continues to expand. We look forward to learning the latest as recommendations from the MGD Workshop sponsored by the Tear Film and Ocular Surface Society will soon be released. ■

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# Side Bar 1 – New Products Released this Fall: TOBRADEX® ST Suspension and SYSTANE® Balance Lubricant Eye Drops

Two new treatments have become available this fall: TOBRADEX® ST Suspension and SYSTANE® Balance Lubricant Eye Drops.

TOBRADEX® ST Suspension is a fixed combination antibiotic (tobramycin) and steroid (dexamethasone) for the management of anterior blepharitis. It is formulated with xanthan gum and contains half the concentration of dexamethasone compared with the original formulation of TOBRADEX® Suspension. Both antibiotic and anti-inflammatory components penetrate the eyelid extremely well.5 The thicker drop allows patients to place it more accurately on affected lids to ensure the medicine is getting right to the area of need.

SYSTANE® Balance is a new artificial tear formulation for patients with MGD and posterior blepharitis. It contains a lipid emulsion system and a HP Guar-based molecule to create a gel to adhere to the eye's surface. Studies indicate this product significantly improves the length of time that a lipid layer covers the eye and increases tear break-up time.[6]

"Research" continued from page 1 ▼

Syndrome Foundation has not reduced funding for research and is holding the line on its research grants in spite of the current economy," says Steven Taylor, CEO of the SSF. "However, overall, we remain very concerned about young investigators turning away from research as their chosen career path when research funds are becoming more and more limited, and we are also worried about established investigators who cannot remain in research for the same reason. This makes donations for research critically important so that research in Sjögren's continues now and in the future."

The SSF is fortunate to be able to maintain its research program this year due to a special donation from the Galewood Foundation, which is funding two of this year's grantees. The Galewood Foundation also funded two grantees last year. Their generous donation follows a similar gift from the Leach Family which funded an Innovative Concept Grantee for two years. Finally, the SSF applauds grantee Sara Michie, who donated her second year's grant funding back to the SSF so that the Foundation could offer an additional grant this year. Donations such as these allow the Foundation to continue encouraging researchers to pursue investigations in Sjögren's in the hope of better understanding the disease and bringing new therapies to market.

## 2010 SSF Research Grant Awards

The SSF awarded seven grants this year. These grants are offered for projects conducted in the United States in the amount of $35,000 per year for up to two years. Each application is appraised by top scientists from around the world during three rounds of review, and the final selections are made based on scientific quality, innovation and the most critical needs of Sjögren's patients. Grantees' project summaries can be viewed at http://www.sjogrens.org/research.

### Research Grant – Gene Therapy

Cuong Nguyen, BS, PhD
University of Florida, College of Dentistry, Gainesville, Florida

*"Suppression of TH17 Cells Using IL-27 Gene Therapy: A Potential Therapeutic Approach for the Treatment of Sjögren's Syndrome Patients"*

*Supported by the Galewood Foundation*

An abnormal feature of Sjögren's is the accumulation of immune cells in the saliva- and tear-producing glands. Dr. Nguyen and colleagues recently reported that certain immune cells that infiltrate these glands belong to a subset of the newly-described cell population known as TH17 cells. These cells secrete factors that regulate immune cells and cause tissue destruction. TH17 cells are

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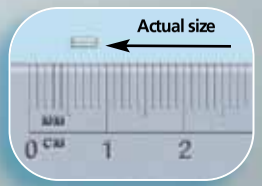


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†Multicenter, 2-visit, 4-week, single-arm study conducted in moderate to severe Dry Eye patients who had previously been using ATs (N=520). Results are based on 418 patients who completed the study.

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**Please see brief summary of Prescribing Information on adjacent page.**

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All-Day Relief

*"Research" continued from page 4 ▼*

normally controlled by a cytokine known as Interleukin-27 (IL-27); however, this regulation is lost in autoimmune diseases.

To investigate the role of IL-27 in Sjögren's, Dr. Nguyen will determine if IL-27 treatment can suppress TH17 cell activity by using a gene therapy approach in an animal model of primary Sjögren's. This project could lay the foundation for gene therapy in patients.

### Research Grant – Genetics in Sjögren's

Kathy Moser, BS, PhD
The Oklahoma Medical Research Foundation, Oklahoma City, Oklahoma

*"The Genetic Basis of Human Sjögren's Syndrome"*



Essentially all traits, including susceptibility to disease, are influenced by inherited genetic variation. We are certain that multiple genes are involved in the development of Sjögren's; however, less than 1% of the estimated 25,000 human genes have ever been tested for a connection with this disease. As a result, the fundamental cause of this complex disorder remains unknown. Powerful tools are now available that allow researchers to comprehensively screen all genes for a potential role in disease. Dr. Moser plans to test essentially every gene for association with Sjögren's.

Photo: UCSF Documents, Media & Mail

### Research Grant – Epigenetics, or How Gene Behavior Can Change

Lindsey Criswell BA, MD, MPH, Dsc
University of California, San Francisco

*"Epigenetic Profiling of Multiple Cell and Tissue Types in Sjögren's Syndrome"*

In addition to the genes we inherit, the way in which those genes express themselves can contribute to disease development. This new and burgeoning field is called "epigenetics." Newly available tools are available that will allow investigators to identify epigenetic mechanisms in complex autoimmune diseases such as Sjögren's. Epigenetic modifications do not affect genetic sequence, but they do play a critical role in gene regulation. The identification of unique epigenetic profiles in SS will significantly transform our understanding of Sjögren's.

### Research Grant – Mechanisms in Developing Dry Eye

Sunil Chauhan DVM, PhD
Schepens Eye Institute,
Boston, Massachusetts

*"Mechanism and Functional Relevance of Corneal Lymphangiogenesis in Dry Eye"*

The autoimmune attack on tear-secreting glands and ocular surface leads to dry eye disease (DED) – a hallmark of Sjögren's, which in severe cases can lead to significant discomfort, visual impairment and blindness. However, the precise mechanism of dry eye development is poorly understood. Dr. Chauhan hypothesizes that dry eye induces growth of corneal lymphatic vessels which allow immune cells in the cornea to more easily migrate into lymphoid tissues, where they activate the autoimmune disease process. He plans to delineate how lymphatic vessels are formed in the cornea in dry eye and proposes that blocking these lymphatic vessels could provide a powerful means of suppressing the generation of autoreactive immune cells and ocular surface inflammation in Sjögren's.

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## Q *I understand there is a new flu vaccine for the 2010-11 flu season. Do you recommend it for Sjögren's patients?*

A As a person with Sjögren's Syndrome you are wondering about whether or not you should have a flu shot this year.

First it's good to have some information about the flu vaccine itself. The seasonal flu vaccine protects against three influenza viruses that research indicates will likely be most common during the upcoming flu season. The 2010-2011 flu vaccine will protect against 2009 H1N1, and two other influenza viruses (an H3N2 virus and an influenza B virus). Each influenza virus has a H and a N determinant which are variable. The viruses in the vaccine change each year based on international surveillance and infectious disease experts estimations about which types and strains of viruses will circulate in the next year. Due to the high mutation rate of the flu virus a particular vaccine formulation is effective for at most about a year. About two weeks after getting the flu vaccine, a person's body will build up antibodies against the flu virus strains that are in the vaccine.

### *There are two main vaccines.*

The "flu shot" — an inactivated vaccine (containing killed virus) that is given with a needle. The flu shot is approved for use in people older than 6 months, including healthy people and people with chronic medical conditions.

The nasal-spray flu vaccine —a vaccine made with live, weakened flu viruses that do not cause the flu (sometimes called LAIV for "live attenuated influenza vaccine" or FluMist®). LAIV (FluMist®) is approved for use in healthy people 2-49 years of age who are not pregnant. It is not recommended for people with compromised immune systems.

So what if you don't get the flu shot? Worldwide, seasonal influenza kills an estimated 250,000 to 500,000 people each year. The majority of deaths in the United States occur in adults age of 65 and over, however, people with chronic disease can be at more risk of complications of the flu. Even if you are not at higher risk of complications, you may live with someone who is, and you could expose that person to the flu if you contract it.

What symptoms do you get with the flu? You may experience high fever, sore throat, generalized body aching, headache, and cough. I contracted the flu in 1975 when I was an intern, and felt so bad that if I had died then I wouldn't have minded it. I have gotten the flu shot every year since.

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# DRY MOUTH

## Learn to manage it 3 ways

Dry mouth associated with Sjögren's is more than just uncomfortable and frustrating. When your body can no longer produce enough protective saliva, you are more likely to have cavities, mouth infections and bad breath. Because dry mouth is an ongoing condition with Sjögren's, it helps to develop an ongoing daily routine in each of the following 3 management areas:

1. **Soothing & Moisturizing:** While sipping water can help, water doesn't lubricate the way saliva does. For symptom relief throughout the day use a moisturizing liquid or gel that has supplemental proteins and enzymes. Keep a portable moisturizing spray on hand to provide soothing relief on-the-go. For night-time relief, consider a soothing moisturizing gel to help keep your mouth moist.
2. **Daily Cleaning:** When you don't have enough saliva, food and bacteria can stick to your teeth causing plaque build-up, bad breath, and other problems. Keep your mouth clean by using fluoride toothpaste and a mouthwash without harsh ingredients. Products formulated specifically for dry mouth should be alcohol and detergent (SLS) free so they won't irritate your mouth.
3. **Saliva Stimulation:** Your saliva not only flushes away odor-causing bacteria, it protects and lubricates your mouth. For oral dryness, stimulate saliva by chewing sugar-free gum containing xylitol.

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# I Stood Up...

## Sjögren's Syndrome Foundation Stands Up in Bethesda, Maryland


We have long been promoting ways for supporters to Shop for Sjögren's – through online retailers like Amazon.com, Walmart and iGive.com that give back a percentage of all purchases to the Sjögren's Syndrome Foundation (visit www.sjogrens.org/shopforsjogrens for more information). But the Foundation and its employees have also been Standing Up and Shopping for Sjögren's, too!

With a small staff running a national organization, it is efficient and easy to do all of the SSF's office supply ordering online. Most of the Foundation's office supplies are purchased through online retailers that partner with iGive.com. Before every office supply is purchased, we visit iGive.com, search for our retailer of choice and click on the link provided. Each order sends up to 2% of that purchase back to the Sjögren's Syndrome Foundation. While that might only be a few dollars at a time, over the course of a full year that can add up to a very sizable donation!

Additionally, most of the staff frequently uses Amazon.com for personal purchases and it has become regular practice to visit www.sjogrens.org/shopforsjogrens and clicking on the Amazon.com link there before making any purchases. The more purchases people make through Amazon's Shop for Sjögren's link, the higher percentage of each purchase will come back to the Foundation. Just in the month of September, over $1,000 of items were purchased through Amazon.com by way of our Shop for Sjögren's link. More than 5% of that was donated back to the Foundation. Think of all the shopping you do online for the holidays and imagine if 5% or more of that was going back to the SSF just by making one extra click! So always visit Shop for Sjögren's or iGive.com before you shop at Amazon.com or to see if the online store you are looking for participates.

The Foundation is always Standing Up for Sjögren's patients in everything we do, and now we are even doing that through our online shopping.

*How are you Standing Up for Sjögren's?*

*"Information You Requested" continued from page 6 ▼*

### Research Grant – T Cell Involvement in the Development of Sjögren's

Jean Oak, MD, PhD
University of California, Irvine

*"Regulatory T Cell Function in a Mouse Model of Sjögren's Syndrome"*

Sjögren's is characterized by lymphocyte-mediated inflammation of lacrimal and salivary glands resulting in dry mouth and dry eyes. The etiology of Sjögren's is complex and likely involves multiple immune cell types including T cells. Dr. Oak and colleagues have discovered that mice whose T cells lack an enzyme called PI3K spontaneously develop several hallmarks of Sjögren's. This mouse model represents a novel tool for studying the pathogenesis of Sjögren's.

Dr. Oak hypothesizes that T cell dysfunction, in particular defects of immunosuppressive regulatory T cells, are an important causative factor in the autoimmune phenotype in these mice. She proposes a series of experiments that will test regulatory T cell function and development.

### Research Grant – Gland Biology and Regeneration

Helen P. Makarenkova, PhD
Neurosciences Research Foundation,
San Diego, California

*"Molecular Mechanisms of Lacrimal Gland Development and Regeneration"*

*Supported by the Galewood Foundation*

Dr. Makarenkova continues her grant on lacrimal gland development and regeneration for a second year in 2010. She hopes that by answering the questions in her proposal, significant advances will be made in the development of new therapies for lacrimal gland regeneration. She is seeking a critical piece of the puzzle that is currently missing in ocular research and Sjögren's. She already has published one article in the first year of her research and just published a second article on her findings this summer.

### Research Grant – Cellular and Molecular Immunology

Sara Michie, MD
Stanford University, Palo Alto, California

*"Lymphocyte Migration to Inflamed Salivary Glands in Sjögren's Syndrome"*

In Sjögren's, white blood cells known as lymphocytes migrate from the bloodstream into salivary glands and lacrimal glands, where they attack and destroy the cells that produce saliva and tears. We have not known, however, which adhesion molecules and activating molecules, known as chemokines, help the lymphocytes migrate from blood vessels into inflamed salivary glands.

Dr. Michie spent the first year of her SSF grant identifying these molecules and will continue her work for a second year. So far, she has found that different chemokines are highly expressed in different and inflamed organs and has refined her aim to pinpoint chemokines that are highly selective in targeting salivary glands, key glands involved in Sjögren's. Dr. Michie published one article shortly after her grant project began and is in the process of seeking a grant from the NIH to continue her grant project after completion of the SSF grant period.

## 2010 SSF Student Fellowships

The Sjögren's Syndrome Foundation is partnering with professional organizations for the first time this year to increase the visibility of Sjögren's and the SSF research program among researchers and clinicians. Two such awards have been made so far: one in ocular research and the second in rheumatology. A third award will be made soon in oral research.

The Bannon Humphery Foundation donated funds that allowed this expansion of the SSF Student Fellowship program, which is paramount to nurturing researchers of the future. Watch the SSF website for the announcement of the winners and their projects. ■

*"Information You Requested" continued from page 7 ▼*

What complications could occur from the flu shot? Soreness at the site of injection is probably the most common adverse event. Occasionally, a systemic effect such as low grade fever, runny nose, or cough may occur. A very very rare neurological complication called Guillan-Barre syndrome has been linked to the flu shot. In this condition, the body's immune system attacks the nerves. Fortunately most people recover, but it can be quite debilitating during the course of the illness.

Who shouldn't get the flu vaccine? People who have had an allergic reaction to a flu shot in the past, people with an allergy to eggs, or a person who previously developed Guillain-Barre syndrome within 6 weeks of getting a flu shot

I recommend that all my patients with Sjögren's get the flu shot each year. Save yourself the misery, the inconvenience, the risk of infecting a love one, and the chance of dying this coming flu season: get the flu shot. ■

*Dan Small, MD*

For patients with Sjögren's syndrome

# DRY-MOUTH SYMPTOMS DON'T HAVE TO BE SO DISTRACTING.

If you experience dry-mouth symptoms due to Sjögren's syndrome, then you already know how distracting these can be to your daily life. It might be time to ask about EVOXAC® (cevimeline HCl), a prescription treatment that works by stimulating the production of your body's own natural saliva.

**Talk to your doctor to see if EVOXAC can help, or visit DiscoverEVOXAC.com.**

Please see important information about EVOXAC below.


## Important Safety Information

**What is EVOXAC?**

- EVOXAC (cevimeline HCl) is a prescription medicine used to treat symptoms of dry mouth in patients with Sjögren's syndrome.

**Who Should Not Take EVOXAC?**

- You should not take EVOXAC if you have uncontrolled asthma, allergies to EVOXAC or a condition affecting the contraction of your pupil such as narrow-angle (angle-closure) glaucoma or inflammation of the iris.

**What should I tell my Healthcare Provider?**

- Tell your healthcare provider if you have any of the following conditions:
  - History of heart disease;
  - Controlled asthma;
  - Chronic bronchitis;
  - Chronic obstructive pulmonary disease (COPD);
  - History of kidney stones;
  - History of gallbladder stones
- Tell your healthcare provider if you are trying to become pregnant, are already pregnant, or are breastfeeding.
- Tell your healthcare provider about all medications that you are taking, including those you take without a prescription. It is particularly important to tell your healthcare provider if you are taking any heart medications especially "beta-blockers".
- If you are older than 65, your healthcare provider may want to monitor you more closely.

**General Precautions with EVOXAC**

- When taking EVOXAC use caution when driving at night or performing other hazardous activities in reduced lighting because EVOXAC may cause blurred vision or changes in depth perception.
- If you sweat excessively while taking EVOXAC drink extra water and tell your health care provider, as dehydration may develop.
- The safety and effectiveness of EVOXAC in patients under 18 years of age have not been established.

**What are some possible side effects of EVOXAC?**

- In clinical trials, the most commonly reported side effects were excessive sweating, headache, nausea, sinus infection, upper respiratory infections, runny nose, and diarrhea.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch, or call 1-800-FDA-1088.

Please visit www.EVOXAC.com for full Product Information for EVOXAC.

For patients having difficulty affording their Daiichi Sankyo medication, please call the Daiichi Sankyo Patient Assistance Program at 1-866-268-7327 for more information or visit www.dsi.com/news/patientassitance.html.

**Please see a brief summary of Important Information for EVOXAC on the next page.**

Evoxac® (cevimeline HCl) 30 mg Capsules

Brief Summary – See package insert for full Prescribing Information.

# EVOXAC® Capsules

## (cevimeline hydrochloride)

**INDICATIONS AND USAGE**
Cevimeline is indicated for the treatment of symptoms of dry mouth in patients with Sjögren's Syndrome.

**CONTRAINDICATIONS**
Cevimeline is contraindicated in patients with uncontrolled asthma, known hypersensitivity to cevimeline, and when miosis is undesirable, e.g., in acute iritis and in narrow-angle (angle-closure) glaucoma.

**WARNINGS**
*Cardiovascular Disease:*
Cevimeline can potentially alter cardiac conduction and/or heart rate. Patients with significant cardiovascular disease may potentially be unable to compensate for transient changes in hemodynamics or rhythm induced by EVOXAC®. EVOXAC® should be used with caution and under close medical supervision in patients with a history of cardiovascular disease evidenced by angina pectoris or myocardial infarction.

*Pulmonary Disease:*
Cevimeline can potentially increase airway resistance, bronchial smooth muscle tone, and bronchial secretions. Cevimeline should be administered with caution and with close medical supervision to patients with controlled asthma, chronic bronchitis, or chronic obstructive pulmonary disease.

*Ocular:*
Ophthalmic formulations of muscarinic agonists have been reported to cause visual blurring which may result in decreased visual acuity, especially at night and in patients with central lens changes, and to cause impairment of depth perception. Caution should be advised while driving at night or performing hazardous activities in reduced lighting.

**PRECAUTIONS**
*General:*
Cevimeline toxicity is characterized by an exaggeration of its parasympathomimetic effects. These may include: headache, visual disturbance, lacrimation, sweating, respiratory distress, gastrointestinal spasm, nausea, vomiting, diarrhea, atrioventricular block, tachycardia, bradycardia, hypotension, hypertension, shock, mental confusion, cardiac arrhythmia, and tremors.

Cevimeline should be administered with caution to patients with a history of nephrolithiasis or cholelithiasis. Contractions of the gallbladder or biliary smooth muscle could precipitate complications such as cholecystitis, cholangitis and biliary obstruction. An increase in the ureteral smooth muscle tone could theoretically precipitate renal colic or ureteral reflux in patients with nephrolithiasis.

**Information for Patients:** Patients should be informed that cevimeline may cause visual disturbances, especially at night, that could impair their ability to drive safely.

If a patient sweats excessively while taking cevimeline, dehydration may develop. The patient should drink extra water and consult a health care provider.

*Drug Interactions:*
Cevimeline should be administered with caution to patients taking beta adrenergic antagonists, because of the possibility of conduction disturbances. Drugs with parasympathomimetic effects administered concurrently with cevimeline can be expected to have additive effects. Cevimeline might interfere with desirable antimuscarinic effects of drugs used concomitantly.

Drugs which inhibit CYP2D6 and CYP3A3/4 also inhibit the metabolism of cevimeline. Cevimeline should be used with caution in individuals known or suspected to be deficient in CYP2D6 activity, based on previous experience, as they may be at a higher risk of adverse events. In an *in vitro* study, cytochrome P450 isozymes 1A2, 2A6, 2C9, 2C19, 2D6, 2E1, and 3A4 were not inhibited by exposure to cevimeline.

*Carcinogenesis, Mutagenesis and Impairment of Fertility:*
Lifetime carcinogenicity studies were conducted in CD-1 mice and F-344 rats. A statistically significant increase in the incidence of adenocarcinomas of the uterus was observed in female rats that received cevimeline at a dosage of 100 mg/kg/day (approximately 8 times the maximum human exposure based on comparison of AUC data). No other significant differences in tumor incidence were observed in either mice or rats.

Cevimeline exhibited no evidence of mutagenicity or clastogenicity in a battery of assays that included an Ames test, an *in vitro* chromosomal aberration study in mammalian cells, a mouse lymphoma study in L5178Y cells, or a micronucleus assay conducted *in vivo* in ICR mice.

Cevimeline did not adversely affect the reproductive performance or fertility of male Sprague-Dawley rats when administered for 63 days prior to mating and throughout the period of mating at dosages up to 45 mg/kg/day (approximately 5 times the maximum recommended dose for a 60 kg human following normalization of the data on the basis of body surface area estimates). Females that were treated with cevimeline at dosages up to 45 mg/kg/day from 14 days prior to mating through day seven of gestation exhibited a statistically significantly smaller number of implantations than did control animals.

*Pregnancy:*
Pregnancy Category C.
Cevimeline was associated with a reduction in the mean number of implantations when given to pregnant Sprague-Dawley rats from 14 days prior to mating through day seven of gestation at a dosage of 45 mg/kg/day (approximately 5 times the maximum recommended dose for a 60 kg human when compared on the basis of body surface area estimates). This effect may have been secondary to maternal toxicity. There are no adequate and well-controlled studies in pregnant women. Cevimeline should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

*Nursing Mothers:*
It is not known whether this drug is secreted in human milk. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from EVOXAC®, a decision should be made whether 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:*
Although clinical studies of cevimeline included subjects over the age of 65, the numbers were not sufficient to determine whether they respond differently from younger subjects. Special care should be exercised when cevimeline treatment is initiated in an elderly patient, considering the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy in the elderly.

**ADVERSE REACTIONS**
Cevimeline was administered to 1777 patients during clinical trials worldwide, including Sjögren's patients and patients with other conditions. In placebo-controlled Sjögren's studies in the U.S., 320 patients received cevimeline doses ranging from 15 mg tid to 60 mg tid, of whom 93% were women and 7% were men. Demographic distribution was 90% Caucasian, 5% Hispanic, 3% Black and 2% of other origin. In these studies, 14.6% of patients discontinued treatment with cevimeline due to adverse events.

The following adverse events associated with muscarinic agonism were observed in the clinical trials of cevimeline in Sjögren's syndrome patients:

| Adverse Event | Cevimeline 30 mg (tid) n*=533 | Placebo (tid) n=164 |
|---|---|---|
| Excessive Sweating | 18.7% | 2.4% |
| Nausea | 13.8% | 7.9% |
| Rhinitis | 11.2% | 5.4% |
| Diarrhea | 10.3% | 10.3% |
| Excessive Salivation | 2.2% | 0.6% |
| Urinary Frequency | 0.9% | 1.8% |
| Asthenia | 0.5% | 0.0% |
| Flushing | 0.3% | 0.6% |
| Polyuria | 0.1% | 0.6% |

*n is the total number of patients exposed to the dose at any time during the study.

In addition, the following adverse events (≥3% incidence) were reported in the Sjögren's clinical trials:

| Adverse Event | Cevimeline 30 mg (tid) n*=533 | Placebo (tid) n=164 | Adverse Event | Cevimeline 30 mg (tid) n*=533 | Placebo (tid) n=164 |
|---|---|---|---|---|---|
| Headache | 14.4% | 20.1% | Conjunctivitis | 4.3% | 3.6% |
| Sinusitis | 12.3% | 10.9% | Dizziness | 4.1% | 7.3% |
| Upper Respiratory Tract Infection | 11.4% | 9.1% | Bronchitis | 4.1% | 1.2% |
| Dyspepsia | 7.8% | 8.5% | Arthralgia | 3.7% | 1.8% |
| Abdominal Pain | 7.6% | 6.7% | Surgical Intervention | 3.3% | 3.0% |
| Urinary Tract Infection | 6.1% | 3.0% | Fatigue | 3.3% | 1.2% |
| Coughing | 6.1% | 3.0% | Pain | 3.3% | 3.0% |
| Pharyngitis | 5.2% | 5.4% | Skeletal Pain | 2.8% | 1.8% |
| Vomiting | 4.6% | 2.4% | Insomnia | 2.4% | 1.2% |
| Injury | 4.5% | 2.4% | Hot Flushes | 2.4% | 0.0% |
| Back Pain | 4.5% | 4.2% | Rigors | 1.3% | 1.2% |
| Rash | 4.3% | 6.0% | Anxiety | 1.3% | 1.2% |

*n is the total number of patients exposed to the dose at any time during the study.

The following events were reported in Sjögren's patients at incidences of <3% and ≥1%: constipation, tremor, abnormal vision, hypertonia, peripheral edema, chest pain, myalgia, fever, anorexia, eye pain, earache, dry mouth, vertigo, salivary gland pain, pruritus, influenza-like symptoms, eye infection, post-operative pain, vaginitis, skin disorder, depression, hiccup, hyporeflexia, infection, fungal infection, sialoadenitis, otitis media, erythematous rash, pneumonia, edema, salivary gland enlargement, allergy, gastroesophageal reflux, eye abnormality, migraine, tooth disorder, epistaxis, flatulence, toothache, ulcerative stomatitis, anemia, hypoesthesia, cystitis, leg cramps, abscess, eructation, moniliasis, palpitation, increased amylase, xerophthalmia, allergic reaction.

The following events were reported rarely in treated Sjögren's patients (<1%): Causal relation is unknown:

***Body as a Whole Disorders:*** aggravated allergy, precordial chest pain, abnormal crying, hematoma, leg pain, edema, periorbital edema, activated pain trauma, pallor, changed sensation temperature, weight decrease, weight increase, choking, mouth edema, syncope, malaise, face edema, substernal chest pain

***Cardiovascular Disorders:*** abnormal ECG, heart disorder, heart murmur, aggravated hypertension, hypotension, arrhythmia, extrasystoles, t wave inversion, tachycardia, supraventricular tachycardia, angina pectoris, myocardial infarction, pericarditis, pulmonary embolism, peripheral ischemia, superficial phlebitis, purpura, deep thrombophlebitis, vascular disorder, vasculitis, hypertension

***Digestive Disorders:*** appendicitis, increased appetite, ulcerative colitis, diverticulitis, duodenitis, dysphagia, enterocolitis, gastric ulcer, gastritis, gastroenteritis, gastrointestinal hemorrhage, gingivitis, glossitis, rectum hemorrhage, hemorrhoids, ileus, irritable bowel syndrome, melena, mucositis, esophageal stricture, esophagitis, oral hemorrhage, peptic ulcer, periodontal destruction, rectal disorder, stomatitis, tenesmus, tongue discoloration, tongue disorder, geographic tongue, tongue ulceration, dental caries

***Endocrine Disorders:*** increased glucocorticoids, goiter, hypothyroidism

***Hematologic Disorders:*** thrombocytopenic purpura, thrombocythemia, thrombocytopenia, hypochromic anemia, eosinophilia, granulocytopenia, leucopenia, leukocytosis, cervical lymphadenopathy, lymphadenopathy

***Liver and Biliary System Disorders:*** cholelithiasis, increased gamma-glutamyl transferase, increased hepatic enzymes, abnormal hepatic function, viral hepatitis, increased serum glutamate oxaloacetic transaminase (SGOT) (also called AST-aspartate aminotransferase), increased serum glutamate pyruvate transaminase (SGPT) (also called ALT-alanine aminotransferase)

***Metabolic and Nutritional Disorders:*** dehydration, diabetes mellitus, hypercalcemia, hypercholesterolemia, hyperglycemia, hyperlipemia, hypertriglyceridemia, hyperuricemia, hypoglycemia, hypokalemia, hyponatremia, thirst

***Musculoskeletal Disorders:*** arthritis, aggravated arthritis, arthropathy, femoral head avascular necrosis, bone disorder, bursitis, costochondritis, plantar fasciitis, muscle weakness, osteomyelitis, osteoporosis, synovitis, tendinitis, tenosynovitis

***Neoplasms:*** basal cell carcinoma, squamous carcinoma

***Nervous Disorders:*** carpal tunnel syndrome, coma, abnormal coordination, dysesthesia, dyskinesia, dysphonia, aggravated multiple sclerosis, involuntary muscle contractions, neuralgia, neuropathy, paresthesia, speech disorder, agitation, confusion, depersonalization, aggravated depression, abnormal dreaming, emotional lability, manic reaction, paroniria, somnolence, abnormal thinking, hyperkinesia, hallucination

***Miscellaneous Disorders:*** fall, food poisoning, heat stroke, joint dislocation, post-operative hemorrhage

***Resistance Mechanism Disorders:*** cellulitis, herpes simplex, herpes zoster, bacterial infection, viral infection, genital moniliasis, sepsis

***Respiratory Disorders:*** asthma, bronchospasm, chronic obstructive airway disease, dyspnea, hemoptysis, laryngitis, nasal ulcer, pleural effusion, pleurisy, pulmonary congestion, pulmonary fibrosis, respiratory disorder

***Rheumatologic Disorders:*** aggravated rheumatoid arthritis, lupus erythematosus rash, lupus erythematosus syndrome

***Skin and Appendages Disorders:*** acne, alopecia, burn, dermatitis, contact dermatitis, lichenoid dermatitis, eczema, furunculosis, hyperkeratosis, lichen planus, nail discoloration, nail disorder, onychia, onychomycosis, paronychia, photosensitivity reaction, rosacea, scleroderma, seborrhea, skin discoloration, dry skin, skin exfoliation, skin hypertrophy, skin ulceration, urticaria, verruca, bullous eruption, cold clammy skin

***Special Senses Disorders:*** deafness, decreased hearing, motion sickness, parosmia, taste perversion, blepharitis, cataract, corneal opacity, corneal ulceration, diplopia, glaucoma, anterior chamber eye hemorrhage, keratitis, keratoconjunctivitis, mydriasis, myopia, photopsia, retinal deposits, retinal disorder, scleritis, vitreous detachment, tinnitus

***Urogenital Disorders:*** epididymitis, prostatic disorder, abnormal sexual function, amenorrhea, female breast neoplasm, malignant female breast neoplasm, female breast pain, positive cervical smear test, dysmenorrhea, endometrial disorder, intermenstrual bleeding, leukorrhea, menorrhagia, menstrual disorder, ovarian cyst, ovarian disorder, genital pruritus, uterine hemorrhage, vaginal hemorrhage, atrophic vaginitis, albuminuria, bladder discomfort, increased blood urea nitrogen, dysuria, hematuria, micturition disorder, nephrosis, nocturia, increased nonprotein nitrogen, pyelonephritis, renal calculus, abnormal renal function, renal pain, strangury, urethral disorder, abnormal urine, urinary incontinence, decreased urine flow, pyuria

In one subject with lupus erythematosus receiving concomitant multiple drug therapy, a highly elevated ALT level was noted after the fourth week of cevimeline therapy. In two other subjects receiving cevimeline in the clinical trials, very high AST levels were noted. The significance of these findings is unknown.

Additional adverse events (relationship unknown) which occurred in other clinical studies (patient population different from Sjögren's patients) are as follows:

cholinergic syndrome, blood pressure fluctuation, cardiomegaly, postural hypotension, aphasia, convulsions, abnormal gait, hyperesthesia, paralysis, abnormal sexual function, enlarged abdomen, change in bowel habits, gum hyperplasia, intestinal obstruction, bundle branch block, increased creatine phosphokinase, electrolyte abnormality, glycosuria, gout, hyperkalemia, hyperproteinemia, increased lactic dehydrogenase (LDH), increased alkaline phosphatase, failure to thrive, abnormal platelets, aggressive reaction, amnesia, apathy, delirium, delusion, dementia, illusion, impotence, neurosis, paranoid reaction, personality disorder, hyperhemoglobinemia, apnea, atelectasis, yawning, oliguria, urinary retention, distended vein, lymphocytosis

*The following adverse reaction has been identified during post-approval use of EVOXAC®. Because post-marketing adverse reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.*

**Post-Marketing Adverse Events:** *Liver and Biliary System Disorders:* cholecystitis

**MANAGEMENT OF OVERDOSE**
Management of the signs and symptoms of acute overdosage should be handled in a manner consistent with that indicated for other muscarinic agonists: general supportive measures should be instituted. If medically indicated, atropine, an anti-cholinergic agent, may be of value as an antidote for emergency use in patients who have had an overdose of cevimeline. If medically indicated, epinephrine may also be of value in the presence of severe cardiovascular depression or bronchoconstriction. It is not known if cevimeline is dialyzable.

℞ Only

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Edison, NJ 08837

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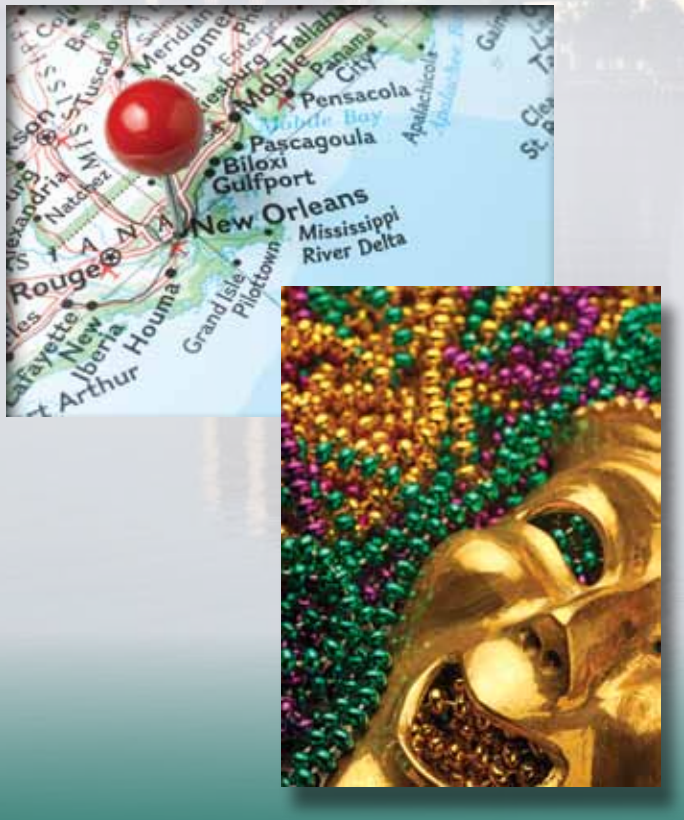
# *Live, Learn & Share*




This January, come to vibrant, festive New Orleans and take control of your health by learning the most up-to-date information from the brightest minds in Sjögren's.

Our *Live, Learn & Share* seminars are the best one-day Sjögren's patient seminars in the country. They have helped thousands gain a better understanding of Sjögren's and will help you, too. Our panel of medical experts will address an array of Sjögren's topics; plus, you'll have the rare chance to meet and share tips with fellow Sjögren's patients.

If you want to be your own best advocate by gaining a thorough understanding of all the key aspects of Sjögren's syndrome, then this one-day seminar is for you.

Sjögren's Syndrome Foundation

## NEW ORLEANS PATIENT SEMINAR
SATURDAY, JANUARY 29, 2011

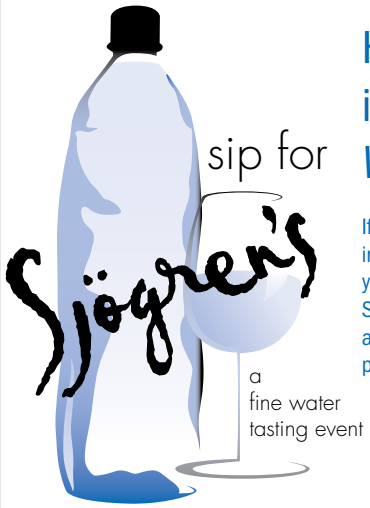
**FEES** – Note: Early Bird Deadline is January 10th, 2011

| | January 10th and before | January 11th and after |
|---|---|---|
| **SSF Members & Guests** | $65 per person | $85 per person |
| Non-Members | $90 (includes one-year membership) | $110 (includes one-year membership) |

**Call Today**
to reserve your place.
**800-475-6473**

- *A fee of $25 will be charged for all seminar registration cancellations. Refund requests must be made by January 10, 2011. After that date, we are sorry but no refunds will be made.*
- *Dietary Requests: Unfortunately, we cannot accommodate all special dietary requirements. We can accommodate vegetarian or gluten-free dietary requests. If you require a vegetarian or gluten-free meal option, please contact Stephanie Bonner at the SSF office (800-475-6473 ext. 210) by January 21st.*
- *A limited number of rooms are available at the Four Points by Sheraton New Orleans Airport hotel, 6401 Veterans Memorial Boulevard, Metairie, Louisiana 70003, at the SSF rate of $119 per night plus tax if reservations are made by January 5, 2011. To make room reservations, please call the hotel directly at 504-885-5700 and refer to the group name "Sjögren's Syndrome Foundation" for the discounted rate.*

**QUESTIONS?** *Call 800-475-6473 or visit www.sjogrens.org*




## Host an event in your area... *We'll help.*

If you are interested in organizing a *Sip for Sjögren's* event in your area, please contact Pat Spolyar, Director of Awareness, at 800-475-6473, ext. 221 or pspolyar@sjogrens.org.

Sjögren's Syndrome Foundation

## *Legacy of Hope*

If you would like to receive information on how you can *Leave a Legacy* to support the Sjögren's Syndrome Foundation's critical research initiatives or to support one of our many other programs, please contact Steven Taylor at 800-475-6473.

*Leave A Legacy – Remember Us in Your Will*

## in memoriam

**In Memory of Billie Margaret Wagner**
Cathy Alford
Lori & Richard Backous
Betty Bishop
Dorothy Brock
Mary Ann Cobb
Kelley & Teena Gamble
Theresa & William Green
George W. Lach
Dotty Marston
Bryan & Leigh New
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Norman Meier
Kevin & Cherri Noel
Owen Electric Cooperative, Inc
Paula Satterwhite
Stephen & Lauren Senvisky
Kim & Dorothy

**In Memory of Florence Stoltenberg**
Jo L. Giessner

**In Memory of Goldie Levin**
Tom Blanco
Rob & Juliana Bloom
Arnie & Linda Rosenberg

**In Memory of Grace Matsuoka**
Ken & Susan Gross

**In Memory of Margaret Mirabelli**
Nan & Gary Cameron

**In Memory of Maria Campanella**
Trudy Campbell

**In Memory of Rose Fisichelli**
The Rabinowitz Family

**In Memory of Ruth Dionne**
Rosalie Geller
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Ken & Valerie Carter
Thomas Edmondson
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## in honor

**In Honor of Alecia Goudy**
Joan McDougal

**In Honor of James & Diane Lawlor's Wedding**
E. Saqqal

**In Honor of Jennifer Unger's Birthday**
Deborah Sellmeyer

**In Honor of Lynn-Anne Spitzer**
Renee Merkur

**In Honor of Mary Wyman's Birthday**
Isabella W. Horsky

**In Honor of Mr. & Mrs. Mort Weisenfeld's Birthdays and Anniversary**
Bert Cohen

**In Honor of Renee Garrick's Birthday**
Alissa Gilles
Margo & Steve McFadden
Deborah Morris

**In Honor of Waltraud Schlanzky's Birthday**
Paula Peterson

# What's really causing your dry eyes?

## Introducing SYSTANE® BALANCE Lubricant Eye Drops — for dry eyes associated with MGD.


**Your dry eye symptoms may be caused by meibomian gland dysfunction (MGD). MGD is a common type of dry eye that often affects sufferers with Sjögren's Syndrome.**[1] MGD is associated with insufficient oil getting to the tear film. This causes increased tear evaporation, which results in signs and symptoms of dry eye.

SYSTANE® BALANCE Lubricant Eye Drops was specifically designed for dry eye patients with MGD. SYSTANE® BALANCE works by restoring the oil layer and re-establishing the natural tear film to relieve your symptoms.

**Talk to your doctor today about MGD, and find out if SYSTANE® BALANCE Lubricant Eye Drops is right for you.**


1. Hom MM et al. Prevalence of meibomian gland dysfunction. *Optometry and Vision Science*. 1990;67(9):710-2. Shimazaki J et al. Meibomian gland dysfunction in patients with Sjögren syndrome. *Ophthalmology*. August 1998;105(8):1485-8.
2. Survey of Ophthalmologists and Optometrists, Harris Interactive®, December 2009.


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# Nashville Isn't Just the Capital of Country Music,

## *it's also the home of the Country Music Marathon and Half-Marathon*

Team Sjögren's

Nashville 2011

Join *Team Sjögren's* and train to run or walk in the 2011 Country Music Marathon & Half-Marathon in Nashville on April 30, 2011.

**We are looking for 25 inspired individuals** to join us as we begin to train for this challenge. We understand that not all Sjögren's patients are able to run or walk in a marathon, so we hope you will extend this invitation to family members as well as friends who may be interested in participating in this challenge!

***To sign up, contact Elyse Gorfain directly at 800-475-6473 ext. 217 or egorfain@sjogrens.org***