

# The Moisture Seekers



www.sjogrens.org

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The "Best Of" Issue: For this month's issue, the Foundation looked over the last several years of "Information You Requested" and "Ask the Staff", and pulled together the most popular questions and answers. In this issue, you will find a variety of inquiries covering various Sjögren's symptoms as well as Foundation activities.



## Best of "Information You Requested"

**Q** Without saliva, almost everything I eat tastes bland. Is there a way I can regain some of my sense of taste so that I can enjoy food the way I used to before I got Sjögren's?

**A** Research has shown that Sjögren's syndrome patients have an increased incidence of taste disorders – both diminished taste (hypogeusia), loss of taste (ageusia), and altered or abnormal taste (dysgeusia). A great deal of the problem comes from a deficiency of saliva. Flavors in food need to be in solution to be fully tasted; that is one of the important functions of saliva. Saliva also helps protect the mucosa and oral structures, including the taste buds. Finally, saliva helps carry food and flavors across the tongue and the taste buds where it can be tasted. Without adequate saliva, there are many ways that taste can suffer.

A full evaluation is recommended since it has been reported that taste also may be affected by medications and by a number of medical conditions. Clinical examination and diagnostic procedures may identify other potential causes for taste complaints such as nasal polyps, viral infection,

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## Best of "Ask the Staff"

*How do I log in to the Member Community on sjogrens.org?*

All members of the Sjögren's Syndrome Foundation have access to the member section of our website, sjogrens.org, as well as the ability to buy books and audio CDs with their member discount at our SSF Store.

The Member Community contains a lot of great information including the latest issue of *The Moisture Seekers*, an archive of every issue dating back to January 2008, an archive of all the Information You Requested questions and answers published in the newsletter over the last few years, and an updated version of our Product Directory. But to ac-

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Elaine K. Harris in 1983

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*"Information You Requested" continued from page 1 ▼*

oral candidiasis, neoplasia, malnutrition, metabolic disturbances, or chemical and physical trauma. Also, complaints of taste loss need to be differentiated from alterations in flavor perception, which is primarily related to your sense of smell.

There is no specific treatment for the taste disorders found in Sjögren's syndrome. However, using liquids to wet the food in your mouth may help increase the taste. You can also try increasing the seasoning on foods and see if it improves the taste. However, be careful not to use excessive amounts of sugar or salt, which can have negative health consequences. Since a reduction in salivary flow may concentrate electrolytes in the saliva, resulting in a salty or metallic taste, drinking plenty of fluids while eating may help reduce dysgeusia.

Although it is controversial, some authors recommend zinc supplements in cases of taste problems. Using an over-the-counter preparation like Z-BEC, one tablet per day, will assure that you are receiving adequate amounts of zinc.

~ Philip C. Fox, DDS

### **Q** Is it recommended/or important to have dental sealants placed on teeth?

**A** Yes. Sealants are generally a good idea even for adults. While primarily performed as a preventive strategy in children, adults with higher risk for caries (like Sjögren's) may benefit from having sealants placed to add extra protection from dental caries.

~ Nelson L. Rhodus, DMD, MPH, FICD

### **Q** As a newly diagnosed Sjögren's patient, what should my biggest concern be?

**A** As a patient newly diagnosed with Sjögren's syndrome, your greatest challenge will be to find a provider(s) experienced in the management of this disorder. Your healthcare professionals must work with you to assess your symptom severity as well as the activity and/or involvement of your eyes, mouth, and internal organs. Keep in mind that about 4-5% of Sjögren's syndrome patients develop non-Hodgkin's B-cell lymphomas as a complication of the disease. Therefore, examination of the salivary and lymph glands (usual sites for lymphomas) and testing for blood markers (e.g. complement C4, cryoglobulins) can be helpful. Early diagnosis is the key to successful management. In Sjögren's, there are no cures but we do have a variety of treatments available to help most Sjögren's-related problems. The SSF also has a variety of materials available to help educate both professionals and patients who are interested in learning more about the disease.

~ Frederick B. Vivino, MD, FACP

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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:

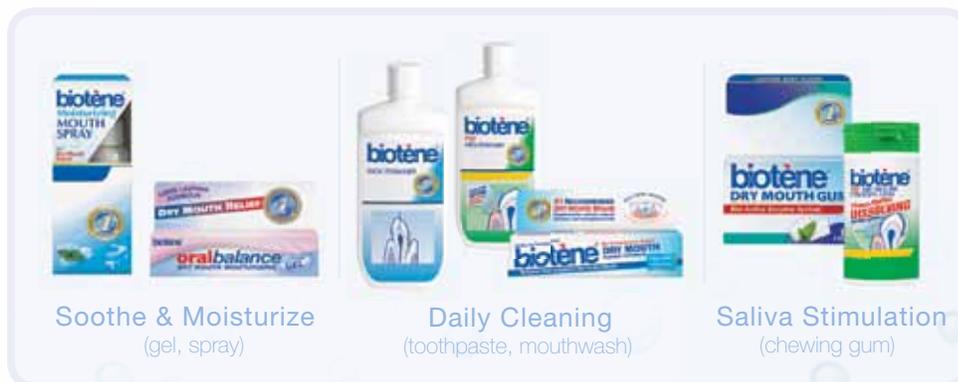
**1. Soothing & Moisturizing:** While sipping water can help, water doesn't lubricate the way saliva does. For symptom relief throughout the day use a moisturizing liquid or gel that has supplemental proteins and enzymes. Keep a portable moisturizing spray on hand to provide soothing relief on-the-go. 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.

Only Biotène, with its protein-enzyme formulations, offers products in each of the 3 management areas.

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#1 FOR DRY MOUTH MANAGEMENT

"Information You Requested" continued from page 2 ▼

## **Q** What about lymphoma? What are the chances I'll get it? Am I going to die from Sjögren's?

**A** Sjögren's syndrome is not life threatening. It is, however, life altering. That said, Sjögren's patients do have an increased chance of developing B-cell lymphoma. The first study connecting the two diseases was conducted more than 40 years ago, and in the years since, we've learned a lot more about the connection. For instance, we've been able to find that the markers that indicate an increased risk of developing lymphoma are not present in all Sjögren's patients. Using these markers, we now can identify those patients who have a greater risk of developing lymphoma and monitor these patients more carefully. It is also important to note that even in the Sjögren's patients who present with these markers, the risk of developing lymphoma is relatively low.

~ Philip C. Fox, DDS

## **Q** What are the treatments for Sjögren's syndrome?

**A** Over the years, great progress has been made in the development of Sjögren's treatments. There are treatments that help manage the symptoms of Sjögren's and others that help to minimize the damage from the exocrine dysfunction. There are drugs that are specifically indicated for the treatment of dry eye and dry mouth in Sjögren's syndrome, and we are entering an era of new therapies with biological agents that will address the underlying processes within the body that cause the signs and symptoms of this disorder. Although these agents might not have the capacity to cure the disease, we can start to envision the possibility of therapies that allow for a remission of the disease so that function of the affected organ systems can be restored over time.

There are many treatments available to help manage the dryness symptoms of Sjögren's including rinses, gels, sprays, emollients, eye drops, artificial salivas, sugarfree gums and mints. There also are FDA-approved systemic secretagogues available that are specifically indicated for treating symptoms of oral dryness in Sjögren's — Pilocarpine (Salagen®) and Cevimeline (Evoxac®) — both of which can increase salivary output and reduce symptoms of dryness and, in some cases, be helpful in relieving eye dryness. Topical cyclosporine — Restasis® — which reduces inflammation, may be used for treatment of the dry eye. Additionally, there are an increasing number of products designed to minimize some of the oral damage associated with Sjögren's. These include supplemental fluoride to reduce dental caries, re-mineralizing solutions for the teeth, and topical and systemic anti-fungals.

Your physician also might prescribe disease-modifying anti-rheumatic drugs like Plaquenil, which — although not indicated specifically for Sjögren's — can reduce the rheu-

matic symptoms associated with Sjögren's, such as fatigue and vasculitis.

Recently, there is a lot of interest in newer biologic anti-B-cell agents. B-cells are lymphocytes found infiltrating the exocrine glands of Sjögren's patients, so scientists are exploring ways to prevent or reduce this infiltration by using agents which deplete B-cells. Rituximab (Rituxan®) has been studied in a number of small but carefully controlled studies and the results have been very promising.

~ Philip C. Fox, DDS

## **Q** For a dry eye Sjögren's patient, what are the pros and cons of Punctal plugs?

**A** Punctal plugs have both pros and cons. The pros are that they are a safe method to retain tears on the ocular surface and have value in relieving symptoms when tear production is borderline or if the duration of applied tear substitutes needs to be prolonged. They are helpful as adjunctive treatment in the management of dry eye disease.

The cons are that when applied in the presence of inflammation that can occur as part of dry eye disease, they may aggravate symptoms by allowing the inflamed tear to have prolonged contact with the surface of the eye. Therefore, my recommendation is to treat the underlying inflammation before placing the plugs. Another con is that they can fall out and need frequent replacement. Rarely, the plug can provoke a localized inflammatory reaction in the tissue of the eyelid and produce a granuloma at the opening of the tear drainage puncta. On balance, punctal plugs are a useful adjunctive treatment for dry eye disease but should be used in conjunction with other therapies to control inflammation.

~ Gary Foulks, MD

## **Q** How do you handle vaginal dryness and genital pain?

**A** Making sure you have a gynecologist who is in tune with what you are experiencing is of prime importance. Vaginal dryness can often be caused by aging, decreased hormone levels, and infection. These elements can also be a source of pain in the genital area and during intercourse. This is not an uncommon problem for women with Sjögren's syndrome.

Assure that your doctor is checking for infection, particularly yeast. She/he should be sending a culture and looking at your vaginal swab under a microscope. Yeast infections can be difficult to treat and may require higher and more frequent doses of antifungal medication. Sometimes it is necessary to combine antifungals to eliminate the infection. If yeast and other infections are ruled out, your doctor should be looking for signs of inflammation to the tissues in the area and try to determine a reason for the inflammation.

There are numerous products available over the counter and via prescription to treat vaginal dryness. Your doctor may order a topical or intravaginal estrogen preparation. Vaginal moisturizers are available for daily use and lubricants are available for use during intercourse. Your approach to these products should be the same as finding the right artificial tear or saliva substitute – trial and error. Keep trying products until you find one that works.

Sometimes your doctor may not be able to determine the source of your pain. If you are not obtaining relief from the above, you may need to see a vaginosis specialist or a gynecologist who specializes in pelvic pain problems.

The SSF carries a book titled *The Vulvodynia Survival Guide* that can be ordered online or by calling the office. Other online sources of information are: [www.vulvodynia.com](http://www.vulvodynia.com), [www.nva.org](http://www.nva.org), [www.pelvicpain.org](http://www.pelvicpain.org) and [www.issvd.org](http://www.issvd.org).

~ Lynn M. Petruzzi, RN

## **Q** *I have heard some patients have started IVIG therapy for their Sjögren's. What is this?*

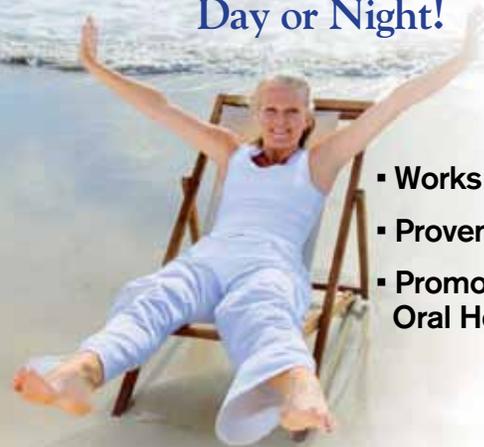
**A** Intravenous immune globulin (IVIG) is an immunosuppressant agent, a type of antibody preparation made from purified serum of normal blood donors. It is currently FDA-approved for treatment of many different disorders including Kawasaki disease, common variable immunodeficiency syndrome, B-cell chronic lymphocytic leukemia, and idiopathic thrombocytopenic purpura. It also is used in bone marrow transplant recipients to prevent certain complications. Additionally, it appears to be useful for treatment of many other immune-mediated diseases, including Sjögren's syndrome. In Sjögren's patients, IVIG is most often used to treat painful peripheral neuropathy (nerve damage in the legs due to inflammation) and thrombocytopenia (low platelet counts). IVIG therapy typically is administered over three to four days once monthly for several months and usually is well tolerated. However, as with any treatment, side effects may occur and include headaches, flushing, dizziness, joint or muscle pain, allergic reactions and, in rare cases, kidney failure. Patients with deficiency of an antibody called IgA (can be tested with blood) are particularly susceptible to side effects and should not receive IVIG unless directed otherwise by their physician.

~ Frederick B. Vivino, MD, FACP

## **Q** *Is a lip biopsy 100% accurate?*

**A** The short answer is "yes ...and no!" The lip biopsy, technically a labial minor salivary gland biopsy, is the single most accurate means of diagnosing the salivary exocrine component of Sjögren's syndrome. However, it is not sufficient alone to establish a diagnosis of the entire syndrome.

## Dry Mouth? Time-Released Relief Day or Night!



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**QUANTUM HEALTH**

In Sjögren's syndrome, there are characteristic changes in the minor salivary glands that can be seen when the tissues are fixed, stained and examined microscopically. Specifically, certain salivary cells are lost (acinar cells) and prominent collections (foci) of inflammatory cells arise which cluster around other salivary (ductal) cells. This is termed by pathologists a "peri-ductal mononuclear cell infiltrate with acinar dropout." The pathologist actually assigns a score to the lip biopsy based on the amount of inflammatory infiltration. While the changes seen are characteristic of Sjögren's syndrome, there are other conditions, such as graft-versus-host disease, hepatitis C and HIV-salivary gland dysfunction, in which a lip biopsy may appear similar on a routine exam. It is important to rule out these situations during diagnosis. If the changes in the minor glands appear to be the result of Sjögren's syndrome,

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one must still have evidence of other exocrine involvement (lacrimal gland) in order to establish a definitive diagnosis of Sjögren's. The lip biopsy is accurate in diagnosing salivary involvement in Sjögren's syndrome and is a critically important part of the clinical evaluation.

The question that often arises is what does it mean when the symptoms and other tests are very suggestive of Sjögren's syndrome – but the lip biopsy is negative? Patients may have dry eyes and a dry mouth, both subjective complaints and measurable decreases in tears and saliva, but the lip biopsy does not show the characteristic tissue changes or there are changes present but they are too mild. Patients – and their doctors – ask, "is this Sjögren's syndrome?"

There are a number of reasons why the lip biopsy may be negative. First, the individual may not have Sjögren's syndrome. There are many causes of dry eyes and mouth, and it is important to search for these as a possible explanation. It would be a mistake to overlook another condition. Second, one could have Sjögren's syndrome but minimal labial minor gland involvement. With time, a subsequent biopsy might be found to be positive. It is important to remember that the current classification criteria for Sjögren's syndrome do not demand a positive biopsy to be considered a definitive case of Sjögren's. The presence of specific serum autoantibodies (SS-A (Ro) and/or SS-B (La)) may substitute for the positive lip biopsy as a required component. So, you may be diagnosed with Sjögren's syndrome without a positive lip biopsy.

Additionally, there are a number of possible technical explanations for a negative biopsy. There may be an insufficient number of minor glands in the specimen. This is often dependent on the procedure used and the experience of the surgeon. (The pathologist needs at least 4-6 minor glands for accurate reading.) Also, all minor glands in an individual are not involved to the same extent. One often can see areas of intense involvement adjacent to relatively normal-appearing tissue. Therefore, the results may be skewed due to sampling error – that is, by chance the sample may be a section with little inflammation. If the specimen had been taken an inch to either side, the results might be different. This is why obtaining a representative number of glands to examine is important. It is also possible that medications the patient has taken could influence the specimen, particularly anti-inflammatory agents. Finally, studies also have shown that different pathologists may score the same tissue differently.

In practice, grading biopsies is not an exact science, unless extremely detailed and time-consuming methods are used. If the results of the biopsy do not match the clinical picture, it may be worthwhile to have the specimen re-read.

So, while a positive lip biopsy in a patient in whom confounding conditions have been ruled out is a very reliable indicator of the salivary component of Sjögren's syndrome, a negative finding does not eliminate the possibility of a diagnosis of Sjögren's. Diagnosis can be difficult, since there is no single test for Sjögren's syndrome and the condition can present in so many different ways. Regardless of the cause, symptoms and signs must be managed and good communication with your doctor is essential. The lip biopsy is a very important tool in the evaluation of Sjögren's syndrome, but it represents only a part of the diagnostic picture.

~ Philip C. Fox, DDS

**Q** What are some questions that I should ask before going on prednisone or other steroid treatments?

**A** Prednisone and other corticosteroids (especially at higher doses) are among the fastest acting and most potent immunosuppressive therapies available. In Sjögren's syndrome these drugs have proven to be useful for management of inflammatory joint and muscle pain, fatigue, swollen glands, and serious internal organ involvement. However, like every therapy, steroids can have both short- and long-term side effects. Therefore, you should ask your physician the following questions in order to better understand the benefits and risks of treatment:

- What symptoms will improve if I decide to take this treatment?
- How long will it take to see benefit?
- What dose of prednisone will I be taking and is it considered high, medium or low?
- How long will therapy be required?
- What are the most common short-term side effects?
- What side effects should I expect if I need this treatment long-term?
- Can I do anything to prevent side effects?
- How will side effects be monitored?

~ Frederick B. Vivino, MD, FACP

**Q** Do you recommend flu shots for Sjögren's patients?

**A** I recommend that most of my patients with Sjögren's syndrome get a flu shot unless they are allergic to eggs, have had a reaction to the vaccine previously, or have other



**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](mailto:pspolyar@sjogrens.org).

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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](http://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](http://www.FDA.gov/medwatch), or call 1-800-FDA-1088.

Please visit [www.EVOXAC.com](http://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/patientassistance.html](http://www.dsi.com/news/patientassistance.html).

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

**EVOXAC**<sup>®</sup>  
(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 CYP3A4 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 (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 Flashes	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, hypertension, 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, 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, thrombocytopenia, 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, hypoglycemia, hyperlipemia, hypertriglyceridemia, hyperuricemia, hypocalcemia, hypokalemia, hyponatremia, thirst

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

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

**Nervous Disorders:** carpal tunnel syndrome, coma, abnormal coordination, dyesthesia, dyskinesia, dysphonia, aggravated multiple sclerosis, involuntary muscle contractions, neuralgia, neuropathy, hyperkinesia, 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 overdose 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.

### Rx Only

#### Distributed and Marketed by:

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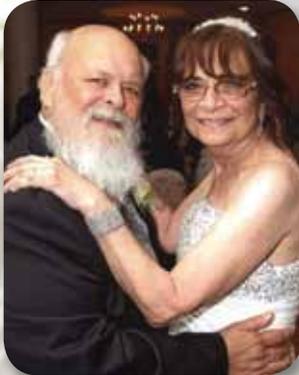


For additional information  
please call toll free:  
1-877-437-7763

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# I Stood Up...

Meet Diane Bilotti Lawlor, Staten Island, New York



## How will you Stand Up?

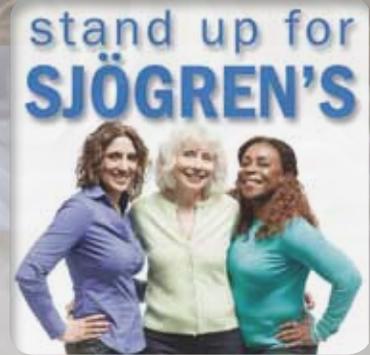
Ever wonder where and how you could spread awareness about Sjögren's syndrome?

Diane Bilotti came up with a first for SSF: at her wedding!

How did she do it? First, Diane made a donation to the SSF in honor of her upcoming marriage to James Lawlor. This got her thinking about how she could raise awareness at her wedding. She contacted the Foundation and after tossing around a few ideas she decided to give each guest a bottle of water and a *What is Sjögren's?* brochure.

The Foundation made up cards which said, "In Honor of the Marriage of Diane and James Lawlor a donation may be made to the Sjögren's Syndrome Foundation." On the reverse side of the card were facts about Sjögren's. Diane purchased bottled water and tied the card to each of them with colored ribbon that coordinated with her attendants' dresses.

This past August, Diane Bilotti and James Lawlor were married in Staten Island, New York. Diane *Stood Up for Sjögren's* by telling her guests about Sjögren's and how it had impacted her life. Many of her guests ended up making donations in honor of their marriage.



"Ask the Staff" continued from page 1 ▼

cess all of this information, and to receive discounts at the SSF Store, you will need to log in to our website.

When your registration is processed by the Sjögren's Syndrome Foundation, you should receive an e-mail from our website notifying you of your username and password. If you have this e-mail, just visit our Member Community at <http://www.sjogrens.org/home/member-community>. You will be prompted to enter a username and password and you can use the information provided in the e-mail.

If you never received this e-mail, or cannot find it, just send an e-mail to us at [info@sjogrens.org](mailto:info@sjogrens.org) requesting your login information, and we will send it to you within 24 hours.

Adam Gerard, Vice President of Operations

### How do I list the Sjögren's Syndrome Foundation in my will?

Each year, the Sjögren's Syndrome Foundation benefits from patients and/or their loved ones remembering the SSF in their wills. To take part and leave your legacy, all you need to do is ask your lawyer to add the SSF to your will by using the Foundation's name, address and Tax ID#. (provided below). You can work with your lawyer and financial advisor to decide how best to leave your legacy. You can restrict your bequest to research or leave it for basic support of the Foundation's education and awareness initiatives.

By remembering the SSF in your will, you will be leaving a legacy for years to come as your support will help future Sjögren's patients.

If you have questions, or if your attorney would like to learn more, please contact me by phone at 301-530-4420 ext. 211.

Here is how to list the SSF:

Sjögren's Syndrome Foundation, Inc.  
6707 Democracy Blvd • Suite 325  
Bethesda, Maryland 20817  
301-530-4420  
Tax ID #11-2779073

Steven Taylor, CEO

### How do you choose a location for the seminars and conferences?

The SSF's patient seminars and conferences are the best way to learn more about Sjögren's syndrome. The Foundation is very fortunate to have a group of dedicated volunteers who comprise the SSF Education Committee, which is responsible for the planning and oversight of all of our public education programs.

After a detailed search process, the Education Committee determines a seminar/conference site location approximately 12–18 months in advance of the program.

continued page 12 ▼

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

health issues that are a contraindication to the vaccination. But it is always best to discuss the vaccination with your physician.

The side-effects of the vaccine, including achiness at the injection site and very mild flu-like symptoms, are certainly an inconvenience. But contracting the influenza virus could cause severe and even life-threatening symptoms for someone with an autoimmune disease. It could lead to a severe febrile respiratory illness that may mean significant time away from work and possibly hospitalization.

I prefer that my patients receive the vaccine in shot form rather than the nasal spray. The shot is inactivated virus particles, while the nasal form is live virus, so there is more risk of developing mild viral symptoms with the nasal administration. This risk associated with the nasal spray vaccination is higher if you are taking medications that can affect the immune system, such as azathioprine, methotrexate, or prednisone. Even still, most patients with Sjögren's who take systemic medications may receive a flu vaccination, but, again, it is always best to discuss this with your physician before taking the injection.

~ Jody K. Hargrove, MD

**Q** *Why are preservative-free artificial tears preferred for Sjögren's patients? Is it true that some preservatives evaporate? How do we know the difference?*

**A** Patients suffering from keratitis sicca (dry eye) associated with Sjögren's syndrome often have disease of the surface of the eye that is severe enough to require frequent (greater than five times per day) instillation of topical medications. If the applied solution contains preservatives, particularly benzalkonium chloride, the amount of preservative can in itself damage the ocular surface cells. For this reason it is often recommended that patients with Sjögren's syndrome use unpreserved drops.

There are many different types of preservative, including some that oxidize quickly once delivered to the eye. Such preservatives may be better tolerated without adding damage to the surface. Nevertheless, the best way to avoid the possible toxic effects of preservatives is to use drops that contain no preservative.

Obviously, care needs to be taken when using unpreserved drops since the possibility of contamination with bacteria, fungus, or amoeba exists. This is why unpreserved solutions are usually packaged in unit-dose containers.

~ Gary Foulks, MD, FACS

**Q** *Is there anything I can do to prevent internal organ involvement due to my Sjögren's?*

**A** Thanks for asking this question, as it is one that physicians with a lot of experience treating people with

Sjögren's feel strongly about, and researchers are working hard on a definitive answer.

I have found that aggressive management of the inflammatory disease manifestations of Sjögren's leads to better patient outcomes, with less major organ system damage and less progression. Therefore, you need to find a physician who has experience treating patients with Sjögren's syndrome aggressively. A perusal of the medical literature, however, will reveal very few double-blind studies demonstrating efficacy of a particular therapy for the manifestations of Sjögren's. Part of the problem is that there has not been a standardization of outcome measures for this disease, so pharmaceutical companies and research organizations have been reluctant to attempt large-scale studies for a disease that does not have standardized outcome measures. Outcome measures have been proposed, and research is being done to validate them, and this will lead to more clinical research to assess specific treatments. When all this is done, I'm sure it will confirm that aggressive management does lead to better patient outcomes with Sjögren's. I have seen similar work done in rheumatoid arthritis patients, and about 20 years after we were using methotrexate aggressively in this disease, our impression of its effectiveness was confirmed by standardized outcome measures, and now methotrexate is recommended as the standard therapy for patients with rheumatoid arthritis.

Why don't more physicians treat patients with Sjögren's more aggressively? Simply, they just don't know any better. They have never received information during their training, and there are few sources of information outside of the Sjögren's Syndrome Foundation that can give them this information after training. Only those who are insightful or have been exposed to physicians knowledgeable in the treatment of Sjögren's will have an understanding of how to treat this disease.

~ Dan Small, MD

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.

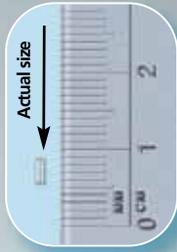
*Leave A Legacy –  
Remember Us in Your Will*

If you drop artificial tears  $\geq 4$  times a day, give yourself

# More Freedom to Go DROPLESS

LACRISERT<sup>®</sup>: All-day dry eye relief in a single daily dose\*

- Significant improvement in symptoms, signs, and activities of daily living<sup>1,2†</sup>
- Dissolves comfortably in the eye to begin all-day relief—like a slow-release artificial tear<sup>2,3</sup>
- No preservatives to cause irritation or damage, even with long-term use<sup>3,4</sup>
- Simple and easy placement<sup>3,4</sup>
- Preferred by nearly 4 in 5 patients over artificial tears<sup>2</sup>



LACRISERT<sup>®</sup> is indicated in patients with moderate to severe Dry Eye syndromes, including keratoconjunctivitis sicca. LACRISERT<sup>®</sup> is indicated especially in patients who remain symptomatic after an adequate trial of therapy with artificial tear solutions. LACRISERT<sup>®</sup> is also indicated for patients with exposure keratitis, decreased corneal sensitivity, and recurrent corneal erosions.

LACRISERT<sup>®</sup> is contraindicated in patients who are hypersensitive to hydroxypropyl cellulose. The following adverse reactions have been reported in patients treated with LACRISERT<sup>®</sup> but were, in most instances, mild and temporary: blurring of vision, eye discomfort or irritation, matting or stickiness of eyelashes and red eyes. If improperly placed, LACRISERT<sup>®</sup> may result in corneal abrasion.

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

For more information, visit [www.LACRISERT.com](http://www.LACRISERT.com) or call 1-877-ATON-549.

Ask your doctor about LACRISERT<sup>®</sup> today!

  
**LACRISERT<sup>®</sup>**  
(hydroxypropyl cellulose ophthalmic insert)

\*Some patients may require twice-daily use for optimal results.<sup>2</sup>

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

*"Ask the Staff" continued from page 9 ▼*

The National Patient Conference (NPC), our annual two-day patient education program, is held in April, "Sjögren's Awareness Month." The committee rotates the location of the NPC from East Coast to West Coast each year, providing the opportunity for as many people as possible in all areas of the country to attend this wonderful program.

Additionally, we hold two regional patient seminars (one-day programs) each year. These seminars are held in various cities throughout the United States. The site location is determined by a number of factors, including area SSF membership, airport proximity and other transportation availability as well as hotel cost.

The Education Committee does an amazing job of researching seminar/conference locations and strives to offer programs that will help those with Sjögren's take control

of their health by learning the most up-to-date information about Sjögren's syndrome!

*Kathy Ivory, Vice President of Field Services*

*I lost my job along with my health insurance, and I don't know what to do about obtaining insurance because of my Sjögren's.*

First, we advise you to investigate your eligibility for COBRA, the Consolidated Omnibus Budget Reconciliation Act of 1985. This federal legislation offers employees the opportunity to continue their employer's group health plan for 18 to 29 months, depending on the employee's circumstances. However, the employee usually must pay for this insurance, which can be high without the typical employer contribution to the cost.

Second, when you apply for insurance, you will use many of the tools we mentioned for applying for Social Security Disability, but you will want to emphasize the opposite health condition and demonstrate that you are not disabled. When you educate the insurance company about Sjögren's syndrome, have your doctor explain that while Sjögren's syndrome is a chronic illness, with knowledge and regular care, patients can, and often do, live without major complications. In addition to your doctor's records, keep a personal diary of symptoms and treatments. If you can demonstrate that you are relatively healthy and functional, this document can help. For example, if you can show capability of performing daily tasks at home and in a work or volunteer environment and a lack of recent need for powerful medications such as prednisone, hospital visits, or expensive testing, your diary can help convince insurance companies that you will not be a high financial risk for them.

We do know, however, that many Sjögren's syndrome patients are, indeed, disabled, and this condition makes finding insurance much more difficult. The Sjögren's Syndrome Foundation has targeted awareness as a top priority. This initiative ultimately should help patients obtain insurance coverage more easily regardless of ability to work and find help with the high cost of healthcare. In September, the Foundation joined the National Health Council in a Town Hall Meeting in New Hampshire to spread the word to presidential candidates about the issue of access to healthcare for those with chronic illnesses. We are working on federal legislation to help patients cover the cost of over-the-counter products for treatment of Sjögren's syndrome, and, we are working to increase recognition among federal officials and congressional members of the high cost of this disease so that healthcare costs can be addressed and more research funded to lead to better treatments and answers.

*Katherine M. Hammitt, Vice President of Research*

# ATON

P H A R M A

Lawrenceville, NJ 08648, USA

Rx Only

**LACRISERT®** (hydroxypropyl cellulose) OPHTHALMIC INSERT

#### DESCRIPTION

LACRISERT® Ophthalmic Insert is a sterile, translucent, rod-shaped, water soluble, ophthalmic insert made of hydroxypropyl cellulose, for administration into the inferior cul-de-sac of the eye.

Each LACRISERT is 5 mg of hydroxypropyl cellulose. LACRISERT contains no preservatives or other ingredients. It is about 1.27 mm in diameter by about 3.5 mm long. LACRISERT is supplied in packages of 60 units, together with illustrated instructions and a special applicator for removing LACRISERT from the unit dose blister and inserting it into the eye.

#### INDICATIONS AND USAGE

LACRISERT is indicated in patients with moderate to severe dry eye syndromes, including keratoconjunctivitis sicca. LACRISERT is indicated especially in patients who remain symptomatic after an adequate trial of therapy with artificial tear solutions. LACRISERT is also indicated for patients with exposure keratitis, decreased corneal sensitivity, and recurrent corneal erosions.

#### CONTRAINDICATIONS

LACRISERT is contraindicated in patients who are hypersensitive to hydroxypropyl cellulose.

#### WARNINGS

Instructions for inserting and removing LACRISERT should be carefully followed.

#### PRECAUTIONS

##### General

If improperly placed, LACRISERT may result in corneal abrasion.

##### Information for Patients

Patients should be advised to follow the instructions for using LACRISERT which accompany the package. Because this product may produce transient blurring of vision, patients should be instructed to exercise caution when operating hazardous machinery or driving a motor vehicle.

##### Carcinogenesis, Mutagenesis, Impairment of Fertility

Feeding of hydroxypropyl cellulose to rats at levels up to 5% of their diet produced no gross or histopathologic changes or other deleterious effects.

##### Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

##### Geriatric Use

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

#### ADVERSE REACTIONS

The following adverse reactions have been reported in patients treated with LACRISERT, but were in most instances mild and transient: transient blurring of vision, ocular discomfort or irritation, matting or stickiness of eyelashes, photophobia, hypersensitivity, edema of the eyelids, and hyperemia.

#### DOSAGE AND ADMINISTRATION

One LACRISERT ophthalmic insert in each eye once daily is usually sufficient to relieve the symptoms associated with moderate to severe dry eye syndromes. Individual patients may require more flexibility in the use of LACRISERT; some patients may require twice daily use for optimal results.

Clinical experience with LACRISERT indicates that in some patients several weeks may be required before satisfactory improvement of symptoms is achieved.

Issued June 2007

References: Koffler BH; for the LAC-07-01 Study Group. Lacrisert (hydroxypropyl cellulose ophthalmic inserts) significantly improves symptoms of dry eye syndrome (DES) and patient quality of life. Poster presented at: Association for Research in Vision and Ophthalmology (ARVO) 2009 Annual Meeting; May 3-7, 2009; Orlando, Florida. 2. Katz JI, Kaufman HE, Breslin C, Katz IM. Slow-release artificial tears and the treatment of keratitis sicca. *Ophthalmology*. 1978;85(8):787-793. 3. Lacrisert [package insert]. Lawrenceville, NJ: Aton Pharma, Inc.; 2007. 4. Hill JC. Slow-release artificial tear inserts in the treatment of dry eyes in patients with rheumatoid arthritis. *Br J Ophthalmol*. 1989;73(2):151-154.

**What can I do to help raise awareness in my community?**

Becoming involved in raising awareness about Sjögren's syndrome and the Foundation in your community will help to educate the public about this chronic illness. Here are a few ways that you can help:

1. Host a Sjögren's table at a local health fair(s) – the office will send you brochures to hand out.
2. Take a supply of brochures when visiting your physician/dentist – the office will send brochures to you.
3. Have your physician/dentist call the office to sign up to receive, free, *The Sjögren's Quarterly*, The Professionals' Resource on Sjögren's Syndrome.
4. Start a FirstGiving page. FirstGiving allows you to easily share your Sjögren's story online with all your friends and family. Visit [FirstGiving.com/ssf](http://FirstGiving.com/ssf) to get started.

6. Make a short presentation to local groups to which you belong, i.e. PTA, Rotary, etc., to educate them about Sjögren's. The office can send you brochures to hand out.
7. Participate in a Sjögren's *Walkabout* or a *Sip for Sjögren's* event in your area. If there isn't one, call the office and find out how you can start one.
8. Think of the SSF for United Way, CFC and Payroll Deductions. If we are not listed on the contribution form, you usually may write in the Sjögren's Syndrome Foundation. Tell your co-workers, friends, and family members how important it is to choose and write in the Sjögren's Syndrome Foundation on their campaign form, too.

Get involved – call the office at 800-475-6473 for help in any of these areas.

*Pat Spolyar, Assistant Director of Awareness*

 **in memoriam**

- In Memory of Anthony DeLeo**  
Steve & Ro Adiletto
- In Memory of Billie Margaret Wagner**  
Yvonne Wagner, Cory Souder, and Amy & Rob Hunter
- In Memory of Buzz Settles**  
Tony & Judy Ptak
- In Memory of Christine Rudny**  
Cathleen Rudny
- In Memory of Christine Taaffe**  
Jaclyn Taaffe
- In Memory of Dr. Darlene Ann Smith**  
Peter & Karen Stanton
- In Memory of Dr. Michael G. Humphrey Beher**  
George & Natalie Beher
- In Memory of Emily Snyder**  
Mr. & Mrs. Jeffrey Klechinski      Franklin & Ruth Snyder
- In Memory of Evelyn Cudney**  
David & Debbie Whittaker
- In Memory of LaRue Horst**  
J. Floyd Wine
- In Memory of Margaret "Mickey" Davitt**  
Teresa A. Heger
- In Memory of Marilyn McFarland**  
Frischhertz Electric Co., Inc.
- In Memory of Martha Clark Peterson**  
Carol Watson
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The Beausang Family      Natalie Concannon  
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Virginia & Marvin Geller      Freda Piecuch & Herbert Gish
- In Memory of Winifred Hagan**  
The Brown Family      Odelia & Jim Ritzcovan

 **in honor**

- In Honor of Barbara Birmingham's 85th Birthday**  
Lis Oliu
- In Honor of Blanche Tyriver**  
Donald King
- In Honor of Bonnie & Steve Litton's 45th Wedding Anniversary**  
Naomi & Neil Arnold
- In Honor of Brenda Satterwhite**  
Mary Thorp
- In Honor of Carol Maletto**  
Mary Hilliker
- In Honor of Dr. & Mrs. Robert Fox**  
Linda Zarzeczny, Q.C.
- In Honor of Elaine Haumann**  
Rowena V. Kather
- In Honor of Guadalupe Garcia**  
Ellen Garcia
- In Honor of Henrietta & John Charton's 45th Wedding Anniversary**  
Carol & Tom Charton
- In Honor of Lila Kissin's Birthday**  
Debbi & Ralph Sorrentino
- In Honor of Marlene & Jim Greene's 54th Wedding Anniversary**  
Natalie Roberts
- In Honor of Regina L. Osofsky's Birthday**  
Alan Osofsky
- In Honor of Shani Corbiere's Birthday**  
Steve & Melissa Roney



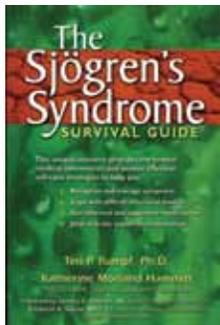
Remember your loved ones and special occasions with a donation to the SSF in their name.

# Make Sure You Have Each of These Best Sellers!

The Sjögren's Syndrome Foundation sells a wide variety of books to make sure all of our members can educate themselves on their disease to be their own best advocates. Below are three of our best-selling books that we have been told by Sjögren's patients are excellent resources and a must for every patient's collection.

## The Sjögren's Syndrome Survival Guide

by Teri P. Rumpf, PhD and Katherine Morland Hammitt

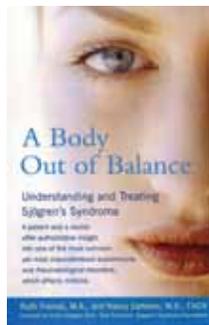


Written together by two Sjögren's patients – one a clinical psychologist and the other a longtime staff member of the Sjögren's Syndrome Foundation – the *Survival Guide* is a complete resource providing vital medical information, research results, and treatment methods, as well as the most effective and practical self-help strategies. The *Survival Guide* is a wonderful resource in a highly readable format addressing all aspects of Sjögren's. It includes clear and practical advice to allow people to take control of this disease and enjoy enormous improvements in their quality of life.

**Member Price: \$13**

## A Body Out of Balance: Understanding and Treating Sjögren's Syndrome

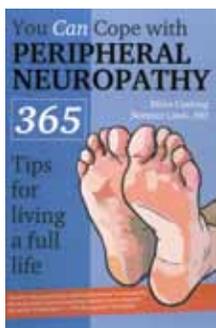
by Ruth Fremes, MA and Nancy Carteron, MD, FACR



Co-written by a woman living with the disease and by a physician who has treated Sjögren's patients, *A Body Out of Balance* provides a comprehensive guide to a wide array of symptoms, traditional and complementary treatments, and invaluable coping methods, so patients may devise a personal treatment plan.

This indispensable resource will enhance awareness and demystify this often misunderstood disorder.

**Member Price: \$10**



## You Can Cope with Peripheral Neuropathy: 365 tips for living a full life

by Mims Cushing and Norman Latov, MD

Peripheral neuropathy is one of the most common, as well as one of the most debilitating and mysterious symptoms of Sjögren's. Written by both a patient-expert and a doctor, this book is a welcome addition to the information on peripheral neuropathy. The book covers such diverse topics as:

- What to ask at the doctor appointments
- Where to find a support group
- Advice for traveling
- Making the house easier to navigate with neuropathy
- Using vitamins and herbs for treatment

*You Can Cope With Peripheripheral Neuropathy* is a compendium of tips, techniques, and life-task shortcuts that will help everyone who lives with this painful condition.

**Member Price: \$16**

This book can be purchased using the order form below, online at [www.sjogrens.org](http://www.sjogrens.org) or by contacting the Sjögren's Syndrome Foundation office at 800-475-6473.

	Non-Member Price	Member Price	Qty	Amount
<b>The Sjögren's Syndrome Survival Guide</b> by Teri P. Rumpf, PhD and Katherine Morland Hammitt	\$15.00	\$13.00		
<b>A Body Out of Balance</b> by Ruth Fremes, MA and Nancy Carteron, MD, FACR	\$13.00	\$10.00		
<b>You Can Cope with Peripheral Neuropathy</b> by Mims Cushing and Norman Latov, MD	\$19.00	\$16.00		
<i>Maryland Residents add 6% sales tax</i>				
<b>Shipping and Handling:</b>	US Mail: \$5 for first item + \$2 for each additional item			
	Canada: \$8 for first item + \$2 for each additional item			
	Overseas: \$18 for first item + \$2.50 for each additional item			
<b>Total Amount</b>				

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# 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.<sup>1</sup> 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.
2. Shimazaki J et al. Meibomian gland dysfunction in patients with Sjögren syndrome. *Ophthalmology*. August 1998;105(8):1485-8.

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**Available without a prescription!**

# Systane® BALANCE

LUBRICANT EYE DROPS

**#1 Doctor Recommended Brand –  
SYSTANE® Dry Eye Products<sup>2</sup>**

**Manufacturer's  
Coupon  
Expires  
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**SAVE  
\$200**

**Inherently Different™**

**OFF SYSTANE® BALANCE  
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Coupon void if altered, copied, sold, purchased, transferred, exchanged or where prohibited or restricted by law. **CONSUMER:** Limit one coupon per specified family purchase. This coupon good only on product sizes and varieties indicated. **RETAILER:** ALCON LABORATORIES, INC. will reimburse you face value plus 8¢, if submitted in compliance with ALCON LABORATORIES, INC. Coupon Redemption Policy dated 1/25/10, available upon request. Consumer must pay sales tax. Good only in USA. Send coupons to ALCON CONSUMER DIVISION, OAS DEPARTMENT #0000, #1 FAWCETT DRIVE, DEL RIO, TEXAS 78840. Cash value 1/20¢.



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*The Moisture Seekers*

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Bethesda, MD 20817

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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*

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 20 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](mailto:egorfain@sjogrens.org)

