

The Moisture Seekers



www.sjogrens.org

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Thyroid Diseases: What You Need to Know

You can't see it, you can't feel it and most people have no idea what it does. In fact, most people don't know about their thyroid unless they've been affected by the often-elusive symptoms of thyroid disease.

The thyroid is a 2-inch-long, butterfly-shaped gland in the front of your neck weighing less than an ounce. It's one of the glands that make up your endocrine system. These glands produce, store and release hormones that travel through the bloodstream and direct the activity of the body's cells.

Thyroid hormones regulate metabolism—the way the body uses energy—and affect nearly every organ in the body. They influence brain development, breathing, heart and nervous system functions, body temperature, muscle strength, skin dryness, menstrual cycles, weight and cholesterol levels.

When the thyroid gland produces more thyroid hormone than the body needs, it can cause many of the body's functions to speed up. This problem is called hyperthyroidism. Too little thyroid hormone, called hypothyroidism, causes many of the body's functions to slow down.

The symptoms of thyroid disease can vary from person to person. Common symptoms of hyperthyroidism are nervousness, irritability, fatigue, muscle weakness, trouble sleeping, heat intolerance, hand tremors, rapid and irregular heartbeat, frequent bowel movements or diarrhea, weight loss, mood swings and goiter, which is an enlarged thyroid that may cause your neck to look swollen.

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Welcoming Our New Board Chairperson

We are excited to introduce Lynn Petruzzi, RN, MSN as the new Chair of the SSF's Board of Directors. Lynn is a Sjögren's patient who is a former nurse and a longtime volunteer for the Foundation. Over her years of service to the SSF, Lynn started our Harrisburg, Pennsylvania Support Group, a very active and vibrant group. Lynn also has volunteered on numerous Foundation committees including our Education and Finance Committees and has also been a vocal advocate for Sjögren's patients. Most recently, Lynn helped launch a successful *Sip for Sjögren's* event in her home town. As Chair, that dedication to the SSF will continue. "I will work my hardest to assure that the SSF remains the national leader for providing information and education to patients with Sjögren's syndrome." ■



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Common symptoms of hypothyroidism are fatigue, weight gain, a puffy face, cold intolerance, joint and muscle pain, constipation, dry and thinning hair, decreased sweating, heavy or irregular menstrual periods, impaired fertility, depression and a slowed heart rate.

Women are much more likely than men to develop thyroid disease. It's also more common among people older than age 60.

It's particularly important if you're a woman with hyperthyroidism to discuss your condition with your doctor before becoming pregnant. Uncontrolled hyperthyroidism raises the chance of miscarriage, preterm delivery and preeclampsia, a potentially serious complication that increases blood pressure.

Thyroid treatments aim to bring thyroid hormone levels back to normal. Treatment depends on the type of thyroid disease and its cause.

If you suspect you might have thyroid disease, talk to a health care professional. Several tests are available to help confirm a diagnosis and find its cause. The American Thyroid Association (which isn't affiliated with NIH) recommends that adults, particularly women, have a blood test every 5 years, starting at age 35, to detect thyroid problems. *Reprinted from NIH News in Health, February 2009.* ■

Concerned About Thyroid Disease?

Women are much more likely than men to develop thyroid disease. Certain other factors can increase your chance of developing thyroid disorders. You may need more regular testing if you:

- have had a thyroid problem before, such as goiter or thyroid surgery
- have a family history of thyroid disease
- have other autoimmune diseases including Sjögren's syndrome, pernicious anemia, type 1 diabetes, rheumatoid arthritis or lupus
- have Turner syndrome, a genetic disorder that affects girls and women
- are older than 60
- have been pregnant or delivered a baby within the past 6 months
- have received radiation to the thyroid or to the neck or chest

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

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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:

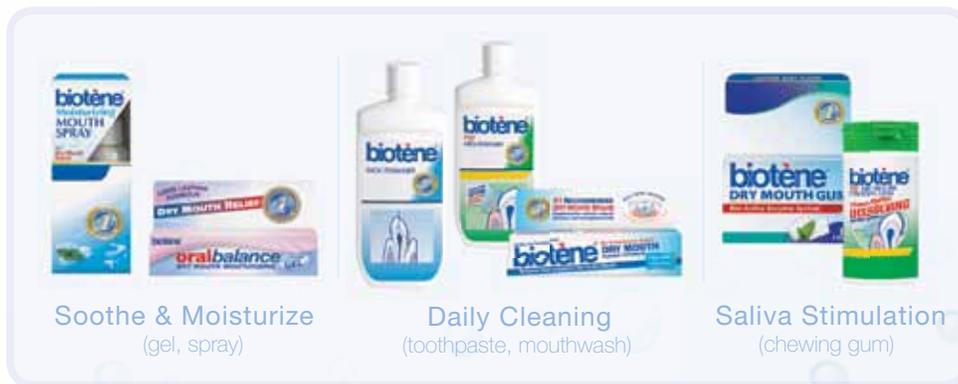
1. Soothing & Moisturizing: While sipping water can help, water doesn't lubricate the way saliva does. For symptom relief throughout the day use a moisturizing liquid or gel that has supplemental proteins and enzymes. Keep a portable moisturizing spray on hand to provide soothing relief on-the-go. For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

Choose the combination of Biotène products that's right for you.



Soothe & Moisturize
(gel, spray)

Daily Cleaning
(toothpaste, mouthwash)

Saliva Stimulation
(chewing gum)



Letter from Sjögren's Syndrome Foundation CEO – Steven Taylor



Dear Friends,

Every two years it is time for new officers to take leadership of the Sjögren's Syndrome Foundation. On July 1st the SSF welcomed our new officers:

Chairperson.....Lynn Petruzzi, RN
Chairperson-Elect.....Lance Forstot, MD
Treasurer.....Kathryn McCarren
Secretary.....Fred Fernandez

Each of them have agreed to volunteer their time to help lead the SSF for the next two years. The officers, along with our other 14 board members, will help set our goals and priorities while always keeping us focused on ensuring we achieve the SSF's mission of helping Sjögren's patients.

The next couple of years are definitely going to be exciting. We have new programs already operating that will change the face of Sjögren's, including our Clinical Practice Guidelines as well as our Clinical Trials Consortium. We also will continue to expand our educational opportunities for patients and their families through our monthly newsletter and our three annual conferences.

In the next few months the SSF will be increasing our intensity around awareness for Sjögren's through our launching of our new Awareness Ambassadors program where patients, family, friends and other volunteers can help by serving as awareness volunteers in their community. Watch TMS for more details and sign up to help. One-by-one, community-by-community, we can really make Sjögren's a household name.

And finally, a special thanks to all of you who help support the Foundation. We couldn't do any of our programs, research, education or awareness without the amazing funds raised by our patients and volunteers throughout the year. Not only will we hold 20 special event fundraisers this coming year, including our Sjögren's *Walkabouts* and our *Sip for Sjögren's*, but we also appreciate those donors that choose to give restricted gifts to research, donate to our annual appeals and expand our network by asking friends and family to donate as well. Every donation helps us continue to increase our commitment to helping patients!

So now, what can you do? I am always asked that question by patients and their family members around the country. How can I make a difference in my small community? How can I really impact the SSF?

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Here are just a few ideas of how you could, in a small way, help us achieve our goals this next year:

- Attend any SSF event or program that takes place in your area, and bring a friend or family member with you.
- Hold a garage sale, lemonade stand or bake sale to benefit the SSF.
- Volunteer to distribute Sjögren's brochures to your local doctors' offices.
- Join the Sjögren's *Walkabout* or *Sip for Sjögren's* committee in your local area.
- Encourage your physician to sign-up for our free healthcare professional newsletter – *Sjögren's Quarterly*.
- Increase Sjögren's awareness by wearing/carrying your Sjögren's apparel while shopping, etc.
- Place a Sjögren's static cling bumper sticker on your vehicle (available for purchase from the SSF).

Together, we can start to make Sjögren's better known throughout the United States. Every time I hear a story about someone getting diagnosed because they read our brochure that they picked up in a physician's office, or hear about someone who discovered the Foundation after seeing another person wearing a Sjögren's *Walkabout* shirt, it makes me realize that our efforts are working.

2010/2011 is going to be another fantastic year. We are proud of what we have accomplished, but we are even more excited about the future and our plans to make the lives of Sjögren's patients a little easier.

Sincerely,

Steven Taylor

Chief Executive Officer



**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.



Friends Helping Friends

Thanks to all who reached out to their personal contacts as part of our *Friends Helping Friends* campaign.

You and your friends helped to raise an outstanding

\$45,314!

Not only did you fundraise but you also increased Sjögren's awareness to countless individuals that we would not have been able to reach without your participation!

From the hundreds of participants entered we randomly selected five individuals to receive a lifetime membership to the Sjögren's Syndrome Foundation! Not only did they win but we also gave them each an additional lifetime membership for a healthcare provider, family member, or friend of their choice!

Congratulations to our Winners!

Elaine - Hopatcong, New Jersey

Lorraine - Burr Ridge, Illinois

Nancy - Durham, North Carolina

Rosalyn - Lakewood Ranch, Florida

Sandra - Ashland, Ohio

A Special Thanks to All who Participated!

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/patientassistance.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 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 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 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, neurotonia, edema, salivary gland enlargement, allergy, gastroesophageal reflux, eye abnormality, migraine, tooth disorder, epistaxis, flatulence, toothache, ulcerative stomatitis, anemia, hypoesthesia, hiccups, 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, hyperglycemia, hyperlipemia, hypertriglyceridemia, hyperuricemia, hypocalcemia, 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, 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

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Daiichi Sankyo Pharma Development, a Division of Daiichi Sankyo, Inc.
Edison, NJ 08837

PRT40 Revised 11/2006 Printed in U.S.A.



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

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I Stood Up...

Meet Estrella Bibbey of Boulder Creek, California

Estrella was determined to make a difference and she did in a BIG way! In April, Estrella contacted the SSF to ask if she could, on the SSF's behalf, organize and recruit friends to participate in an area 6-mile running event that is held every July in California. She wanted to invite some of her friends to join with her to run and to raise funds at the Wharf to Wharf Race as *Team Sjögren's*.

We loved the idea and thought this concept was just great. It was a way to build upon the SSF's plans to expand *Team Sjögren's* while continuing our efforts to raise awareness. Estrella went right to work and immediately started recruiting her friends to join her team.

Estrella's Team members, besides her husband Jerry, were fellow moms who are members of her community "Mommies" group. None of them knew much about Sjögren's, except that Estrella suffered from the chronic disease. After 3 months of training for the 6-mile race, and raising funds for the SSF, they are all now well-versed in Sjögren's.

Estrella set up an event webpage for her team members to use to begin fundraising at www.firstgiving.com/ssf. Each team member received a *Team Sjögren's* t-shirt to wear while training and also to wear on the day of the event. Estrella arranged for her team members to register for the event and had them each set up their own fundraising webpage.

The team met a few times with a trainer who donated his time to help the team members prepare for the walk/run. They trained together with and without their children and strollers. The friends were compelled to make a difference, especially for Estrella and they began with a team goal of raising \$5,000. Each member began to reach out to their personal contacts, sharing information about Sjögren's and collecting donations. Estrella even contacted and gained the attention of the media with a story in the local paper and in the online fitness section of the San Francisco *Examiner*.

On July 25th, in Santa Cruz, California, along with



Estrella and her son, Anderson

Team Sjögren's before the race.

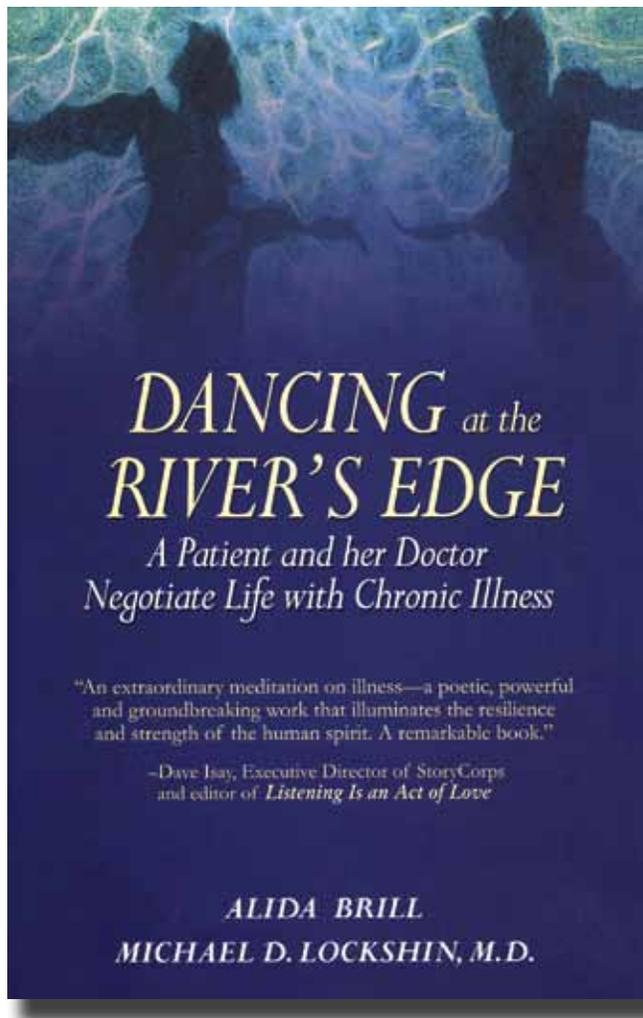


Team Sjögren's moms training.

15,000 other Wharf to Wharf participants, as well as SSF CEO Steve Taylor and his mother who suffers from Sjögren's, Estrella and her Sjögren's California Dreamin' of a Cure Team celebrated their journey of supporting their friend!

Estrella's Team had grown to 14 participants and raised an incredible \$12,711. Thanks, Estrella, for initiating this endeavor and Standing Up to make a difference!

How will you Stand Up?



Dancing at the River's Edge: A Patient and Her Doctor Negotiate Life with Chronic Illness

by Alida Brill & Michael D. Lockshin, MD

Dancing at the River's Edge is a unique dual memoir by Alida Brill, author, social activist and critic, who has endured an incurable illness throughout most of her life, and her doctor, Michael D. Lockshin, MD, a leading expert on autoimmune diseases in women, who has treated Ms. Brill for over thirty years.

Both authors offer a powerful and inspirational testimony from either side of the examining table that speaks directly and honestly to those who deal with being on the "other planet" that is the reality of the chronically ill, as well as to those who care for and give care to millions of people struggling day-to-day with this condition.

Alida Brill, the keynote speaker at the SSF's 2010 National Patient Conference in San Francisco, has had her writing appear in popular and professional periodicals and journals, and she is a frequent guest on radio interview shows and television programs. She has been a featured speaker at a variety of conferences and a guest lecturer at many universities and colleges in the United States and abroad.

Her writing together with her doctor is "poetic, revealing, insightful, and at times shocking in their honest and frank discussion of aspects of chronic disease that are rarely brought out into the open." - From *The New England Journal of Medicine* (August, 2009)

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

	Non-Member Price	Member Price	Qty	Amount
Dancing at the River's Edge by Alida Brill and Michael D. Lockshin, MD	\$16.00	\$14.00		
<i>Maryland Residents add 6% sales tax</i>				
Shipping and Handling:	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			
Total Amount				

Mail to SSF, BB&T Bank · PO Box 890612 · Charlotte, NC 28289-0612 or Fax to: 301-530-4415

Name _____

Address _____

City _____ State _____ Zip _____

Telephone _____ E-Mail _____

Enclosed is a check or money order (in U.S. funds only, drawn on a US bank, net of all bank charges) payable to SSF.

MasterCard VISA AmEx Card Number _____ Exp. Date _____

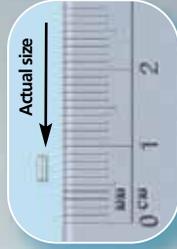
Signature _____ CC Security Code _____

If you drop artificial tears ≥ 4 times a day, give yourself

More Freedom to Go DROPLESS

LACRISERT[®]: All-day dry eye relief in a single daily dose*

- Significant improvement in symptoms, signs, and activities of daily living^{1,2†}
- Dissolves comfortably in the eye to begin all-day relief—like a slow-release artificial tear^{2,3}
- No preservatives to cause irritation or damage, even with long-term use^{3,4}
- Simple and easy placement^{3,4}
- Preferred by nearly 4 in 5 patients over artificial tears²



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.

LACRISERT[®] is contraindicated in patients who are hypersensitive to hydroxypropyl cellulose. The following adverse reactions have been reported in patients treated with LACRISERT[®] 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[®] may result in corneal abrasion.

Please see brief summary of Prescribing Information on adjacent page.

For more information, visit www.LACRISERT.com or call 1-877-ATON-549.

Ask your doctor about LACRISERT[®] today!

*Some patients may require twice-daily use for optimal results.¹
†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.


LACRISERT[®]
(hydroxypropyl cellulose ophthalmic insert)

All-Day Relief

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You can earn a penny for the SSF every time you search on the Internet! GoodSearch.com is a search engine that donates half its revenue to the charities its users designate. Bookmark www.good-search.com as your new search engine and be sure to choose Sjögren's Syndrome Foundation.

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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: Kaffler 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.



in honor

In Honor of Anita F. Abeleda

Patricia Davies

In Honor of Anita Ulloa

Joanne Andrews

In Honor of Dr. Troy Daniels

Bonnie & Steve Litton

In Honor of Irma Rodriguez & Fred Fernandez

Bonnie & Steve Litton

Ann & Mike Miller

In Honor of Jackie Sculli

Steve & Linda Crabtree

In Honor of Kim & Charles Vaughn

Nancy & John Jungman

In Honor of Lynn Petruzzi

Bonnie Litton

In Honor of Margaret Goldsmith

Michael Boehm

In Honor of Nancy Ritchey

Susan Wright

In Honor of Susan Joyce

Louise Sternberg

In Honor of Waltraud Schlanzky

Ingrid Halling

IT'S TIME

United Way • Combined Federal Campaign • State Payroll Deduction

Each fall your local United Way, Combined Federal Campaign, state employee, and private employer payroll deduction campaigns begin. We hope you will remember the Sjögren's Syndrome Foundation when choosing where to allocate your donation.

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.

If your employers will not allow you to write in the Sjögren's Syndrome Foundation, remind them that we are a national non-profit 501(c)(3) organization and qualify for most payroll deduction campaigns. If they need more information, please contact the Foundation at 800-475-6473 and ask for Elyse Jordan.

Just think – every dollar counts.

Last year alone – thanks to those who chose to give through their employer's payroll campaign – the Sjögren's Syndrome Foundation was able to increase its Research and Awareness commitments.

Remember, the Foundation has received the:



Standards of Excellence



in memoriam

In Memory of Barbara McBride
Robin Lorton

In Memory of Darlene Smith
Sofronis & Marlene Babula
JoAnn Szlaga

In Memory of LaRue Horst
Continuing Care Personal Services
Florence A. Finlayson
Susan Horst
Hazel Huffman
Paul & Elizabeth Kipps
Lupus Foundation of Virginia, Roanoke Chapter
Mike & Debby Pafel
Ida Powell
Julia Rader
Anne Whitt

In Memory of Margaret Mirabelli
Amy Sisson & Paul Abell
Nancy Isaacson

In Memory of Margaret Winkler Hartman
Bob & Bette Patton

In Memory of Mary M. Ruth
Melissa, Scott & Noah Messina

In Memory of Nancy E. Andreeko
Andrew Andreeko

In Memory of Sam Schatteu, MD
Vivian Dubose

In Memory of Sharon Lestage
Mary Ann Jurski
Norm & Roberta Mikesell

In Memory of Sharon Marie Brantley
Lisa Coates Chapman
Elviry & Houston Coleman
Glenna Corner
Dorothy Floyd
Barbara Weeks & Tanya Gilliard
Earline Smith

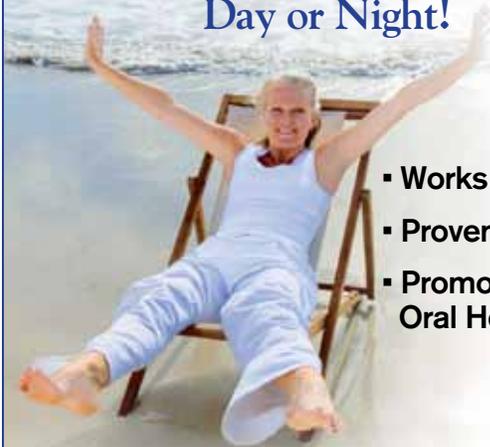
In Memory of Vincent Houston
Irene Hudgston
Hunter College of Business

In Memory of Virginia Winiarski
Judith Sudomier

In Memory of Walter Kram
Trudy Hirsh



Dry Mouth? Time-Released Relief Day or Night!



- Works for Hours
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OraMoist is an innovative, clinically proven approach to treating dry mouth.

OraMoist is a time-released patch that adheres to the roof of the mouth and then slowly dissolves, moistening for hours. The Patch releases a lipid that lubricates the mouth, and Xylitol and enzymes to improve oral health.



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



Live, Learn & Share



This October, come to Windsor Locks, Connecticut and take control of your health by learning the most up-to-date information from the brightest minds in Sjögren's syndrome.

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.



HARTFORD PATIENT SEMINAR SATURDAY, OCTOBER 2, 2010

1 ATTENDEE – complete for each registrant

Attendee Name(s) _____
Attendee Name(s) _____
Street Address _____
City _____ State _____ Zip _____
Telephone _____ E-mail _____

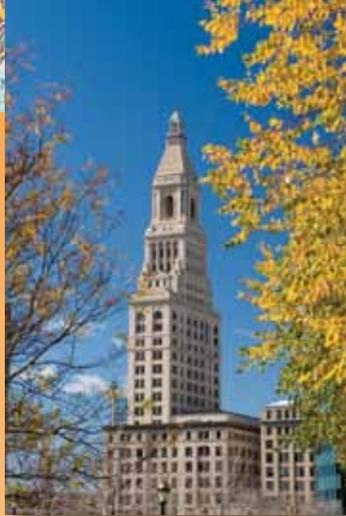
2 FEES – please circle appropriate fee(s) (Note: Early Bird Deadline is September 8, 2010)

	September 8th and before	September 9th and after
SSF Members & Guests	\$65 per person	\$85 per person
Non-Members	\$90 (includes one-year membership)	\$110 (includes one-year membership)
TOTAL:		

3 PAYMENT – Mail to SSF, c/o BB&T Bank · PO Box 890612 · Charlotte, NC 28289-0612 or Fax to: 301-530-4415

Enclosed is a check or money order (in U.S. funds only, drawn on a U.S. bank, net of all bank charges) payable to SSF.
 MasterCard VISA AmEx Card Number _____ Exp. Date _____
Signature _____ CC Security Code _____

- A fee of \$25 will be charged for all seminar registration cancellations. Refund requests must be made by September 8, 2010. 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 September 23rd.
- A limited number of rooms are available at the Sheraton Hotel at Bradley International Airport, Windsor Locks, Connecticut 06096, at the SSF rate of \$99 per night plus tax if reservations are made by September 15, 2010. To make room reservations, please call the hotel directly at 1-860-627-5311 and refer to the group name "Sjögren's Syndrome Foundation" for the discounted rate.



Live, Learn & Share

Sjögren's Syndrome Foundation
Patient Seminar

Sheraton Hotel at
Bradley International Airport

Windsor Locks, Connecticut

Saturday, October 2, 2010

Seminar Topics and Speakers

Overview of Sjögren's Syndrome – Ann Parke, MD

Dr. Parke is Professor of Medicine at the University of Connecticut Health Center at St. Francis Hospital and Medical Center. Dr. Parke also has a clinical practice at St. Francis Hospital. Dr. Parke will present a comprehensive explanation of the range of symptoms that Sjögren's patients experience, explain their causes, and offer practical tips for managing them.

Treatment of Dry Eye in Sjögren's – Peter C. Donshik, MD

Dr. Donshik has practiced medical and surgical ophthalmology in the greater Hartford area since 1976. He sub-specializes in corneal and external diseases of the eye, laser vision correction, contact lenses and corneal transplant surgery. Dr. Donshik lectures nationally and internationally, and is a widely published author with over 100 articles in both national and international journals. This esteemed eye care expert will discuss the latest dry eye therapeutic treatments, covering the extensive range of help available from artificial tears to silicone plugs to systemic drugs to help you manage and treat dry eye.

Research Update – Steven Taylor, SSF Chief Executive Officer

Mr. Taylor will share an update on the Foundation's Research Program and the goals for 2010-2011. Mr. Taylor will discuss how research holds future promise, greater understanding and hope for better therapies for all Sjögren's patients.

The Sjögren's Ripple Effect – Susan Milstrey Wells

Susan Milstrey Wells is an accomplished writer and editor with more than 30 years of experience. A former member of the Sjögren's Syndrome Foundation Board of Directors, Ms. Wells is the author of *A Delicate Balance: Living Successfully with Chronic Illness*. She writes about mental health and homelessness for the federal government and is principal speechwriter for the director of the federal Center for Mental Health Services. Drawing on personal experience, Ms. Wells will enlighten you about the impact chronic illness can have on your relationships with family, friends, and other people in your life. You will appreciate her hard-won wisdom!

Measuring the Activity of Sjögren's Syndrome – Steven E. Carsons, MD

Dr. Carsons is Chief of the Division of Rheumatology, Immunology, and Allergy at Winthrop-University Hospital in Mineola, New York. He is also Associate Chairman of the Department of Medicine and Director of Research at Winthrop-University Hospital, Director of the Clinical and Translational Research Core at Winthrop Research Institute, and Professor of Medicine at State University of New York at Stony Brook. Dr. Carsons will discuss the methods commonly used to measure and manage Sjögren's disease activity.

The Moisture Seekers

Sjögren's Syndrome Foundation Inc.
6707 Democracy Blvd., Ste 325
Bethesda, MD 20817

Phone: 800-475-6473

Fax: 301-530-4415

Don't Forget... Shop for Sjögren's

Shop to benefit the Sjögren's Syndrome Foundation

The Sjögren's Syndrome Foundation has partnered with online retailers who will donate a portion of the value of your purchase to the SSF, so shopping online is now an easy way to contribute to Sjögren's!

Just visit www.sjogrens.org/shopforsjogrens and click through the links provided so that your purchases will benefit the SSF. Some of our partners include:

- ◆ **Amazon.com** is one of the most popular online stores in the world, offering a wide variety of products. Up to 8% of the value of your purchase is donated back to the Foundation.
- ◆ **DentalPlans.com** offers you a discounted dental plan to use along with your dental insurance, or as an alternative to dental insurance. Even if you already have dental insurance, the discounts offered through DentalPlans.com may be used along with your dental insurance for even more savings on your dental care. Just visit www.dentalplans.com/ssf, find a discount dental plan that works for you, and when purchasing use the coupon code SSF10 to receive a 10% discount from the published price. Additionally, 10% of your purchase will be contributed to the Foundation!
- ◆ **Drugstore.com** is a leading online provider of health, beauty, vision, and pharmacy products. The website allows you to shop as if you were at your local drug store, and you can get instant savings while 10% of your purchase benefits the SSF.
- ◆ **Walmart.com** offers access to a wide assortment of products at their everyday low prices, with up to 4% of your purchases being donated to the SSF.
- ◆ **iGive.com** offers exclusive deals with over 700 brand name stores you know and love, with a specified percentage of each purchase coming back to the SSF. Be sure to select "Sjögren's Syndrome Foundation" as your charity of choice. Whenever you return to iGive.com and log in, any shopping you do will benefit the SSF! It's that simple.

Just go to
www.sjogrens.org/shopforsjogrens
and start shopping!

