Moisture Seekers

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She has Sjögren's - Positive Actions and Attitudes that can be Supportive to You Both!

by Fred Fernandez, Member, SSF Board of Directors

or everyone who is the spouse of a Sjögren's syndrome patient, you completely understand that you both have an important role in managing this disease. Few things impact the life and activities of a marriage partnership like the unplanned complications of one of you being diagnosed with an incurable autoimmune disease. Just as with so many things in life, actions and attitude are critical to outcomes and being in control.

With Sjögren's, 90% of the time it is she who has been diagnosed, but make no mistake about it, you both are now faced with learning to deal with the manifestations and what you can do together to keep your life and activities within the acceptable range of your goals as a couple. Each Sjögren's patient is unique in how he or she



What are the long-term effects of using Plaquenil? As an immunosuppressant, does it actually increase the risk of other diseases?

Plaquenil, or hydroxychloroquine (HCO), is an anti-malarial medication that has been proven to be useful in the treatment of patients with rheumatoid arthritis (RA), systemic lupus erythematosus (SLE) and other inflammatory and autoimmune diseases. In Sjögren's syndrome, HCQ is believed to improve oral and ocular (eye) signs and symptoms and has been shown to reduce inflammatory markers in saliva and serum, such as sedimentation rates and C-reactive protein levels. The only clinical trial in which HCQ was compared with placebo prospectively was published in 1993 and reported results on only

19 patients. It did not demonstrate any clinical ocular benefit despite improvements in hyperglobulinemia (increased immunoglobulin levels) and reductions in sedimentation rates. Despite these findings and the absence of any large prospective, placebo-controlled trials, HCQ is frequently used to treat Sjögren's syndrome in academic and private practice settings. It is used to treat many symptoms of Sjögren's syndrome including fatigue, joint symptoms of arthritis and arthralgias (joint pain), dry mouth and dry eyes. Similar to its use in systemic lupus erythematosus, it is felt by many clinicians that it is useful in reducing general Sjögren's "disease activity."

One of the reasons that physicians feel comfortable in prescribing HCQ is its low risk-to-benefit ratio. This means that the side effects of HCQ are mild and infrequent compared with its potential benefits. As with any medication, allergic reactions,



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may be impacted; however, there are many proven actions which have been shown to be immensely helpful in managing life towards normalcy, whatever that is! When you find out, please be sure to let us all know!

The single most important step a spouse of a Sjögren's patient can take is addressing it together, focusing on the positive proactive steps that will make a difference in quality of life for her and you both! But just what does that mean, you ask? It is important that couples decide the answer to this question together and for themselves individually, as the best answers will be as diverse as the individuals involved and the varied ways relationships are constructed.

Since my wife received the diagnosis over 25 years ago, we have engaged in numerous opportunities to learn about Sjögren's and what we can do to manage it. We sought out the best information we could find from many sources and quickly discovered the Sjögren's Syndrome Foundation to be the most helpful resource out there. As a result, we have attended many of the national conferences, made use of the Foundation resources, and have become financial contributors in support of the mission to create awareness and fund research to find a cure. This is a selfish activity we call, "trying to help ourselves." We also work on behalf of the Foundation by volunteering our energy and resources to raise research funds and to co-chair the annual Atlanta *Sip for Sjögren's* fine water tasting event. As I enter my second term as an active member of the SS Foundation board of directors, I have sought to be an integral part of the organization's efforts to serve the patient community, to educate others, and to create greater awareness about this little-known autoimmune disease.

The knowledge we gained includes the importance of proper diet and avoiding foods which contribute to dehydration. We are very specific when ordering food in restaurants and only frequent those which are welcoming to our concern for customizing her food order. We prepare food more often at home where we are in complete control of the content and preparation. We have learned to recognize there are times when our best-made plans might be interrupted by fatigue which can weigh down many Sjögren's patients. Since failing to heed the signs of fatigue only leads to greater exhaustion and weakening of her immune system, we are quick to respond with a change of plans and some needed down time for rest. I look to do small things to help her with this and to insure we do not add even more emotional stress than she might already feel about not being up to doing more.

Another area of importance is to actively participate in addressing your knowledge of Sjögren's by joining her at the doctor's office for visits or attending educational programs like the Sjögren's national or regional conferences or local support group events. Learning about the pathology and what is going on in her body as well as about the various treatments and medications will greatly increase your ability to be constructively helpful

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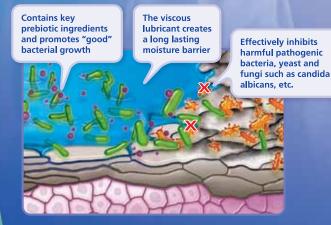
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Paraben/Preservative Free	YES	NØ	NØ	NØ
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and will insure you understand what is going on with her overall health and how you can be supportive. Her best tool, and we recommend everyone do this, is to update her written account of how she is doing between doctor visits and provide this information to each of her doctors along with any questions she has. She always takes notes of each visit and has noticed this helps her to get more thorough responses from the doctors and helps them understand she is taking responsibility and control of her treatment.

So what does addressing it together mean to you? Perhaps, like us, it really is no different than what you would do for any other important issue in your life as a couple. Being a central part of the learning, participat-

ing actively, finding ways in which you each can help create the best possible outcome, making adjustments where needed and planning a life routine which allows you to maximize your success and enjoyment while maintaining the best possible control over her health. Or it might mean taking on a more active role of finding new solutions through supporting research by doing critical fundraising and volunteering your most important resource... time. Your positive actions and attitudes are two areas where as a couple, you have complete control. How well you use this power will help lead you to the best possible outcome. We wish you a successful path in your individual journeys as couples learning to take as much constructive control of Sjögren's as possible.



I Stood Up.... Cheryl Levin, Chicago, Illinois

Meet Cheryl Levin, fundraiser extraordinaire, the top *Sjögren's Walkabout* fundraiser in the nation for 2010. She personally raised a record-breaking \$15,300 for the Chicago Area *Walkabout*.

Cheryl is an active young professional woman, an avid runner who, because of the negative effects Sjögren's has had on her health, has been unable to do the physical activities she loves the most. Even daily routine activities are sometimes impossible. Cheryl did not let this stop her. Sjögren's may have taken a toll on her health, but it has not tackled her spirit.

Cheryl found the strength to fight back and, WOW, she did just that this past November! Her method of fighting back was to reach out to her loved ones and her army of supporters by asking them to contribute to her fundraising efforts for Sjögren's research and education. Many had been watching her struggle with her health, silently wishing for a way they could help their dear friend, sister, daughter and co-worker, but they did not know how. Once she decided to participate, all Cheryl had to do was ask her friends for their support — explain to them what they could do to help and how. Armed with her informative fundraising letters and her personal firstgiving Chicago *Walkabout* webpage, she reached out to her community of friends and family and was stunned by their outpouring of support! Congratulations, Cheryl — you taught us all how to *Stand Up* for Sjögren's!



Cheryl Levin and Vice President of Development Sheriese DeFruscio at the 2010 Chicago Area Walkabout

How will you Stand-Up?

FEBRUARY WALKABOUT EVENTS

Saturday morning, February 12 Sunday morning, February 13

Sarasota Walkabout Orlando Walkabout

Saturday morning, February 26 Phoenix Al

Phoenix Area Walkabout & Autoimmune Disease Health Fair

DeSoto Square Waterford Lakes Town Center Paradise Valley Mall

So many of our patients tell us that their loved ones want to help but don't know how... so consider developing a personal webpage on www.firstgiving.com/ssf and sharing your story with your family and friends. The SSF can supply Sjögren's brochures and sample letters for you to use as well. Remember, the power of our voices can change the face of Sjögren's! Thanks for Standing Up!

"Information You Requested" continued from page 1 ▼

including skin rashes, and non-allergic reactions can occur. The side effect that is of greatest concern is retinal toxicity. Hydroxychloroquine can deposit a pigment on the retina. This is the part of the eye that receives images that are transmitted to the brain resulting in vision. This pigment can interfere with the transmission and impair our vision. With continued treatment, visual loss can develop. Luckily, the pigment deposition and any visual loss are completely reversible with discontinuation of treatment with HCQ. This side effect is very unusual and in a recent study in patients with SLE and RA, documented retinal toxicity was seen in less than 1% of patients treated with HOC, and most were seen after 5-7 years of treatment. As a precaution, patients treated with HCO are advised to get a baseline eye exam prior to starting the drug and then annually thereafter, although the authors of the above-noted study suggest that the guidelines for follow-up be revised in light of their findings and that frequent early follow-up examination may not be necessary. Nevertheless, there is no consensus on when follow-up exams should be performed and, therefore, we would recommend that you defer to the suggestions of your

treating physician and ophthalmologist.

Physicians and patients consider hydroxychloroquine an immunosuppressant medication for lack of a more accurate descriptor. Perhaps an immunomodulatory medication would be a better term. The mechanism of action of HCQ has not been fully elucidated and is still a matter of debate, but it clearly has been shown to have anti-inflammatory properties mediated through modulation of the immune system. Unlike more potent immunosuppressant agents such as corticosteroids, methotrexate, azathioprine, cyclophosphamide, and rituximab, hydroxychloroquine's effects on the immune system are subtle and not as profound. When we consider effects of medications on the immune system, the two side effects that we are most interested in are whether, by potentially decreasing normal immuno-surveillance, they might increase the risk of infection and the development of neoplasm (cancers). There is no evidence that HCQ increases patients' risk of getting infections or increases their risk of developing cancer.



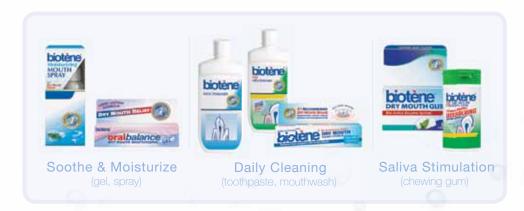
Learn to manage it 3 ways

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.









SSF Personal Support System

Listed below are SSF Contact Persons, members who volunteer to be sources of information for Sjögren's syndrome. Asterisks (*) indicate the location of where SSF Support Group meetings are held.

International support groups are available throughout the world. Please contact our office for specific information.

ALABAMA			DELAWARE		
Daleville	Marilyn Murray*	(334) 598-5387	Newark	Marsha Bates	(302) 593-3179
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Montgomery	Sharon Miller*	(334) 277-2302	FLORIDA	Marialla Carlana	(EC4) 400 0040
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ALASKA	ludy Mastallar	(907) 376-6275	Bradenton/Sarasota	Melody Carpenter Georgene Slepin	(941) 761-1352 (305) 446-4834
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Sparkman	Laurine Langley	(870) 366-4388	North Hutchinson Island	Elizabeth Brinamen*	(772) 595-5873
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Philadelphia	Sandra Pacini*	(215) 672-2983	Spokane Tacoma/Spanaway	Jaqueline Riley Judy Kay Reynolds*	(509) 466-2432 (253) 531-7369
	(phone contact for Philadelph		iacuilla/ Spallaway	Judy Ray Reynolds	(203) 001-1009
Distalance	Barb Barbon	(610) 775-7949	WEST VIRGINIA		
Pittsburgh	Paula Helmick*	(724) 335-1252	Moundsville	Pat Kleinedler	(304) 845-8473
Davis and AManakas areas	Jane Potteiger	(412) 922-9826	W//000NOW		
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	Lupus Fndt./Resource Ctr for Autoimmune Diseases*		Madison	Nancy Johnson*	(608) 332-5928
Wallingford		(888) 995-8787	Milwaukee	Wendy Liedtke*	(414) 541-5857
Wallingford	Ruth Goldman	(610) 441-1441	River Falls	Mimi Trudeau	(715) 425-8183
Washington Crossing	Margo Hartman	or (610) 565-6136			
Washington Crossing	Marge Hartman	(215) 345-8249			
RHODE ISLAND					
North Smithfield	Lynne Messina	(401) 766-8645			
Warwick	Joyce Bert	(401) 738-0857		l'onodo	
				Canada	
SOUTH DAKOTA	0 . 01	(005) 500 0400		ulliuuu	
Beresford	Sue Christensen	(605) 563-2483			
TENNESSEE					
Johnson City	Deborah Harvey*	(423) 946-1750			
Memphis	Betty Wetter	(901) 682-2073	ALBERTA		
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TEXAS	I'. I. F. J.	(540) 055 0040	BRITISH COLUMBIA	Dhallia Hakali	(004) 500 0055
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		(817) 498-6552	Fredericton	Betty Ponder	(506) 450-9929
Conroe/Woodlands	Marilyn Adams*	(281) 298-9196	Fredericton	Betty Ponder	(506) 450-9929
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Reflux and Your Throat

by Soo Kim Abboud, MD, Assistant Professor, Department of Otolaryngology, Head and Neck Surgery, University of Pennsylvania School of Medicine, Philadelphia, Pennsylvania.



OraMoist is an innovative, clinically proven approach to treating dry mouth.

Promotes Oral Health

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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with Sjögren's suffer from gastroesophageal reflux disease (GERD). This can cause a wide variety of symptoms that can be mistaken for other conditions. Symptoms may include persistent heartburn and/or regurgitation of acid, stomach pain, hoarseness or voice change, throat pain, sore throat, difficulty swallowing, sensation of having a lump in the throat, frequent throat clearing and chronic cough (especially at night time or upon awakening).

Tips for combating gastroesophageal reflux in the throat:

- Avoid lying flat during sleep. Elevate the head of your bed using blocks or by placing a styrofoam wedge under the mattress. Do not rely on pillows as these may only raise the head but not the esophagus.
- Don't gorge yourself at mealtime. Eat smaller more frequent meals and one large meal.
- Avoid bedtime snacks and eat meals at least three to four hours before lying down.
- Lose any excess weight.
- Avoid spicy, acidic or fatty foods including citrus fruits or juices, tomato-based products, peppermint, chocolate, and alcohol.
- Limit your intake of caffeine including coffee, tea and colas.
- Stop smoking.
- Don't exercise within one to two hours after eating.
- Promote saliva flow by chewing gum, sucking on lozenges or taking prescription medications such as pilocarpine (Salagen[®]) and cevimeline (Evoxac[®]). This can help neutralize stomach acid and reduce symptoms.
- Consult your doctor if you have heartburn or take antacids more than three times per week. A variety of OTC and prescription medications can help but should only be taken with medical supervision.

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 HCI) is a prescription medicine used to treat symptoms of dry mouth in patients with Sjögren's syndrome.

Who Should Not Take EVOXAC?

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

What should I tell my Healthcare Provider?

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

General Precautions with EVOXAC

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

What are some possible side effects of EVOXAC?

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

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

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

For patients having difficulty affording their Daiichi Sankyo medication, please call the Daiichi Sankyo Patient Assistance Program at 1-866-268-7327 for more information or

visit www.dsi.com/news/patientassitance.html.



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

Covinmentor 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.

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 bron-chitis, or chronic obstructive pulmonary disease.

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

Geriralin. 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,

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 provide

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

Drugs which inhibit CYP2D6 and CYP3A3/4 also inhibit the metabolism of cevimeline. Cevimeline should be used with cau-tion 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 sig-nificant 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 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 esti– mates). 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.

Safety and effectiveness in pediatric patients have not been established.

Although clinical studies of cevimeline included subjects over the age of 65, the numbers were not sufficient to deter-mine whether they respond differently from younger subjects. Special care should be exercised when cevimeline treat-ment 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

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%
Polvuria	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			Bronchitis	4.1%	1.2%
Tract Infection	11.4%	9.1%	Arthra l gia	3.7%	1.8%
Dyspepsia	7.8%	8.5%	Surgical Intervention	3.3%	3.0%
Abdominal Pain	7.6%	6.7%	Fatigue	3.3%	1.2%
Urinary Tract Infection	6.1%	3.0%	Pain	3.3%	3.0%
Coughing	6.1%	3.0%	Skeletal Pain	2.8%	1.8%
Pharyngitis	5.2%	5.4%	Insomnia	2.4%	1.2%
Vomiting	4.6%	2.4%	Hot Flushes	2.4%	0.0%
Injury	4.5%	2.4%	Rigors	1.3%	1.2%
Back Pain	4.5%	4.2%	Anxiety	1.3%	1.2%
Rash	4.3%	6.0%	•		

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

The following events were reported in Sjögren's patients at incidences of <3% and ≥1%: constipation, tremor, abnormal vision, hypertonia, peripheral edema, chest pain, myalpia, fever, anorexia, eye pain, earache, dry mouth, vertigo, sallvary gland pain, pruritus, influenza-like symptoms, eye infection, post-operative pain, vaginitis, skin disorder, depression, hiccup, hyporeflexia, infection, fungal infection, sialoadenitis, otitis media, erythematous rash, pneumonia, edema, salivary gland enlargement, allergy, gastroesophageal reflux, eye abnormality, migraine, tooth disorder, epistaxis, flatulence, toothache, ulcerative stomatitis, anemia, hypoesthesia, cystitis, leg cramps, abscess, eructation, moniliasis, palpitation, increased amylase, exrophthalmia, 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, arrhyth-mia, 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, lleus, irritable bowel syndrome, melena, mucositis, esophageal stricture, esophagitis, oral hemorrhage, peptic ulcer, periodontal destruction, rectal disorder, stomatitis, tenesmus, tongue discoloration, tongue disorder, geographic tongue, tongue ulceration, dental caries

Endocrine Disorders: increased glucocorticoids, goiter, hypothyroidism

Hematologic Disorders: thrombocytopenic purpura, thrombocythemia, thrombocytopenia, hypochromic anemia, eosino-philia, granulocytopenia, leucopenia, leukocytosis, cervical lymphadenopathy, lymphadenopathy

Liver and Billiary 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 principle of the property of the pro aminotransferase)

Metabolic and Nutritional Disorders: dehydration, diabetes mellitus, hypercalcemia, hypercholesterolemia, hyper-glycemia, hyperlipemia, hypertriglyceridemia, hyperuricemia, hypoglycemia, hypokalemia, hyponatremia, thirst Musculoskeletal Disorders: arthritis, aggravated arthritis, arthropathy, femoral head avascular necrosis, bone disorder, bursitis, costochondritis, plantar fascilitis, muscle weakness, osteomyellits, osteoporosis, synovitis, tendinitis, tenosynovitis

Neoplasms: basal cell carcinoma, squamous carcinoma

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

Miscellaneous Disorders: fall, food poisoning, heat stroke, joint dislocation, post-operative hemorrhage Resistance Mechanism Disorders: cellulitis, herpes simplex, herpes zoster, bacterial infection, viral infection, genital moniliasis, sepsis

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

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

Skin and Appendages Disorders; acne. alopecia, burn, dermatitis, contact dermatitis, lichenoid dermatitis, eczema. SMIT and Appelhatages Distributes, active, adoption, outin, definations, contact derinations, inclination derinations, externing further design states of the planus, and discoloration, nail discorder, oncychia, onychomycosis, paronychia, photosensitivity reaction, rosacea, scleroderma, seborrhea, skin discoloration, dry skin, skin exfoliation, skin hypertrophy, skin ulceration, urticaria, verruca, bullous eruption, cold dammy 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

Uncepnital Disorders: epiddymitis, prostatic disorder, abnormal sexual function, amenorrhea, female breast neoplasm, malignant female breast neoplasm, female breast pain, positive cervical smear test, dysmenorrhea, endometrial disorder, abnormal sexual function, amenorrhea, endometrial disorder, obraina cyst, ovarian disorder, genital pruritus, uterine hemorrhage, vaginal hemorrhage, atrophic vaginitis, albuminuria, bladder discomfort, increased blood urea nitrogen, dysuria, hematuria, micturition disorder, rephrosis, nocturia, increased onoprotein introgen, pyelonephritis, enal calculus, abnormal renal function, renal pain, strangury, urethral disorder, abnormal urine, urinary incontinence, decreased triving flow pruries. decreased urine flow, pyuria

In one subject with lupus crythematosus 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:

Into Hopging Pademics are as union-flowed in Cholinergics 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 phosphotase, failure to thrive, abnormal platelets, aggressive reaction, amnesia, apathy, delirium, delusion, dementia, illusion, impotence, neurosis, paranoid reaction, personality disorder, hyperhemoglobinemia, annea, atelectasis, yawning, oliguria, urinary retention, distended vein, hymphocytosis

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

R_ℓ Only

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memoriam

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Elaine & Larry Levin

In Memory of Diane Irene Weiner

Mr. & Mrs. Robert E. Lee Bentz

In Memory of Glenda Delott

Richard Delott

In Memory of Jean M. Saj

Cynthia M. Harder Anthony Missana

In Memory of Joan Elizabeth Pientka

Steve Ciha

Bob Feller & Family

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Rich & Linda Marth

The Neubauer Family

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In Memory of Morry Martin

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In Memory of Rose Marie LeBar

Cynthia Kabbe

In Memory of Ruby, our basset hound

Victor & Janice DeWitt

In Memory of Stephanie Schram

Alicia A. Rohrlack

honor

In Honor of Audrey Wiesenfeld's 90th Birthday

Elaine & Herb Harris

In Honor of Dorothy Colhard

Chris Colhard

In Honor of Eileen Bergeron

Stan Hammer Farms

In Honor of Jackie Sciulli - Wishing you a speedy recovery San Diego & Imperial Counties Support Group

In Honor of Jill "The Amazing" Glover

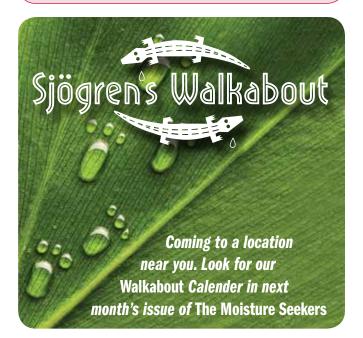
The Warnicks

In Honor of Kim Satterwhite

Cara Brook

In Honor of Mary Sue Newton

Joe Waller







Leave A Legacy – Remember Us in Your Will



As a Sjögren's patient, it's easy to feel confused or overwhelmed by the abundance of information available about the illness and how it affects your body. But here is *Your Passport to Learning* for an educational journey to take control of your health and day-to-day living by learning from the best minds dealing with Sjögren's. This April, join fellow Sjögren's patients and their family members as well as healthcare professionals and other experts who specialize in Sjögren's at the 2011 SSF National Patient Conference in Reston, Virginia (just outside of Washington, DC).

SSF programs are the best Sjögren's patient education opportunities in the country. They have helped thousands gain a better understanding of Sjögren's and will help you, too. This two-day event will feature an array of presentations from the country's leading Sjögren's experts — physicians, dentists, eye care providers, and researchers — who will help you understand how to manage all key aspects of your disease. Presentation topics will include:

Overview of Sjögren's Syndrome
OB-GYN Issues and Sjögren's
Lung Complications
Dry Eye and Dry Mouth Issues

How to Find a Healthcare Professional Knowledgeable about Sjögren's

Neurological Manifestations

Vitamin D Deficiency in Autoimmune Disease

Sjögren's Survival: A Patient Perspective

Overlapping Major Connective Tissue Diseases

Research Update

Aching Joints, Fatigue and Sjögren's

So this April 1-2, we invite you to pick up *Your Passport to Learning* and experience an amazing opportunity to heighten your understanding of Sjögren's at the 2011 National Patient Conference in Reston, Virginia!

Call 1-800-475-6473 or visit www.sjogrens.org today to receive the latest information.

Space is limited. Please register early!

Registration Form

Registration fees include: Lunch each day, snacks and beverages, Friday evening dinner, hand-out material from speakers and entrance to exhibit area on Friday and Saturday.



2011 NATIONAL PATIENT CONFERENCE RESTON, VIRGINIA — APRIL 1-2, 2011

ATTENDEE – complete for each	n registrant		
Attendee Name(s)			
Attendee Name(s)			
	State		
Telephone	E-mail		
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FEES — please circle appropriate	fee(s) (Note: Early Bird Deadline is Mar March 7th and before	(11 7, 2011)	March 8th and after
SSF Members & Guests	\$165 per person		\$185 per person
Non-Members	\$190 per person		\$210 per person
TOTAL:	**** ps. ps.		4-1-1-1-1
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at time, we are sorry that no refunds can	be made.		
etary Requests: Unfortunately, we cannot	accommodate all special dietary requirer	nents. We ca	n accommodate vegetarian or gluten
etary requests. If you require a vegetarian	or gluten-free meal option, please conta	ct Stephanie	e Bonner at the SSF office (800-475-6
t. 210) by March 23rd.			
limited number of rooms are available at	the Hyatt Regency Reston (1800 Preside	ents Street, I	Reston, Virginia 22090) at the SSF ra
129 per night plus tax if reservations are m	ade by March 8, 2011. Call the toll-free	hotel reserva	ation number at 888-421-1442 or cal

Hyatt Regency Reston directly at 703-709-1234 and refer to the group name "Sjögren's Syndrome Foundation" for the discounted rate.

• The Hyatt Regency Reston provides a complimentary shuttle service to/from the Dulles International Airport.

The Moisture Seekers

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

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It's not too late to join us in New Orleans



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

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

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



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

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

Call Today to reserve your place.

800-475-6473

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