

The Moisture Seekers

Sjögren's Syndrome Foundation



www.sjogrens.org

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Sjögren's Top 5: What Your Physician Should be Monitoring For

by Daniel J. Wallace, MD

Patients with Sjögren's usually see their autoimmune treating physician several times a year. Mostly, they are rheumatologists, but can also be primary physicians, internists or subspecialists such as interested pulmonary or hematology doctors. In addition to taking a history, performing a physical examination, or drawing blood tests, are there things that should be specifically looked at or monitored for? This article reviews the top five items.

1. Is there evidence for extraglandular Sjögren's?

Some people with extraglandular Sjögren's may have interstitial lung disease, renal tubular acidosis, swollen lymph glands, or inflammatory scarring of the bile ducts (biliary cirrhosis). Being identified with extraglandular Sjögren's usually warrants systemic immune suppressive therapy with agents such as azathioprine, methotrexate, cyclophosphamide or rituximab.

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Sjögren's and Dry Skin

Dry skin often is overlooked as a major feature of Sjögren's but deserves greater recognition as a frequent issue for patients. Dry skin can occur as the result of an immune dysfunction and destruction of the structures, which moisturizes and lubricates the skin – a process similar to that which causes dry mouth and dry eye in Sjögren's.

These skin structures include the hair and oil glands as well as sweat glands. Once destroyed, these oil and sweat glands cannot be restored. Although most common in fall, winter and early spring, dry skin occurs throughout the year. Areas most often affected are legs, arms and abdomen (especially the beltline/waist).

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The treating physician should use their tools to screen for the spread of Sjögren's to new areas with imaging or laboratory testing, which allows one to be proactive and treat the disease early.

2. Screening for lymphoma

Over a 15-20 year period of observation, 8-15% of Sjögren's patients develop a lymphoma. Screening for symptoms of early lymphoma include asking a patient about swollen glands, fevers, weight loss and new onset of fatigue. A physical examination can detect lymph nodes, evidence for a "wasted" appearance, or an enlarged spleen. I perform a serum protein electrophoresis (a \$30 blood test) on my Sjögren's patients every 6 months. Often, early lymphomas can be detected with the development of an extra protein on this determination, which is known as a "MGUS" or monoclonal gammopathy of uncertain significance. Most Sjögren's associated lymphomas are of a specific variety known as "MALT" that, if identified early, responds well to treatment.

3. Looking for overlapping Sjögren's

Sjögren's patients can have features of other autoimmune conditions such as rheumatoid arthritis, inflammatory myositis, biliary cirrhosis, scleroderma, Hashimoto's thyroiditis or lupus, while still being "mostly" Sjögren's. These features may warrant certain anti-inflammatory interventions. This would include corticosteroids for inflamed muscles, drugs that promote more oxygen to dilate the vessels of the hands for individuals with Raynaud's (often seen with scleroderma or lupus), approaches that halt the development of erosions (bone destruction) with rheumatoid arthritis (e.g., anti-TNFs), ursodiol for biliary cirrhosis, antimalarials for subacute cutaneous lupus rashes in anti-SSA positive patients or thyroid. Identification of a secondary autoimmune overlap can often explain symptoms that may be profound but are not a part of Sjögren's.

4. Don't unnecessarily treat Sjögren's for symptoms that are not related

Sjögren's patients may have high blood pressure, depression and diabetes, as does 25% of the United States. Medications given for these conditions can make dry eye or dry mouth symptoms more severe. Treating such patients with anti-inflammatory medications or diuretics (water pills) is not advisable. Before altering one's Sjögren's medications or their environment, the physician should strive to rule out co-morbidities or co-existing circumstances that may seemingly worsen Sjögren's symptoms.

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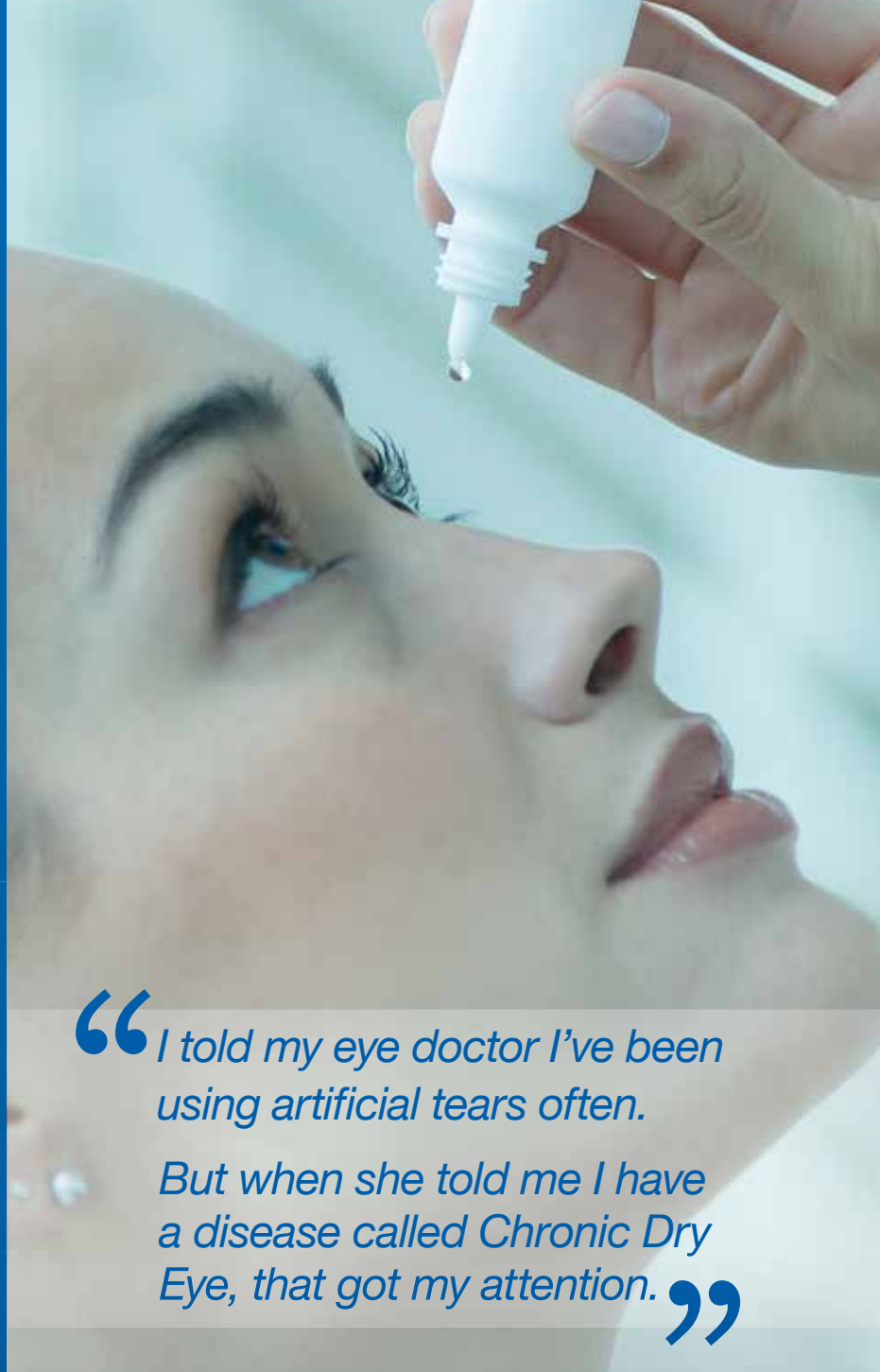
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CONTRAINDICATIONS

RESTASIS® is contraindicated in patients with known or suspected hypersensitivity to any of the ingredients in the formulation.

WARNINGS AND PRECAUTIONS

Potential for Eye Injury and Contamination

To avoid the potential for eye injury and contamination, be careful not to touch the vial tip to your eye or other surfaces.

Use with Contact Lenses

RESTASIS® should not be administered while wearing contact lenses. Patients with decreased tear production typically should not wear contact lenses. If contact lenses are worn, they should be removed prior to the administration of the emulsion. Lenses may be reinserted 15 minutes following administration of RESTASIS® ophthalmic emulsion.

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In clinical trials, the most common adverse reaction following the use of RESTASIS® was ocular burning (17%).

Other reactions reported in 1% to 5% of patients included conjunctival hyperemia, discharge, epiphora, eye pain, foreign body sensation, pruritus, stinging, and visual disturbance (most often blurring).

Post-marketing Experience

The following adverse reactions have been identified during post approval use of RESTASIS®. Because these 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.

Reported reactions have included: hypersensitivity (including eye swelling, urticaria, rare cases of severe angioedema, face swelling, tongue swelling, pharyngeal edema, and dyspnea); and superficial injury of the eye (from the vial tip touching the eye during administration).

USE IN SPECIFIC POPULATIONS

Pregnancy

Teratogenic Effects: Pregnancy Category C

Adverse effects were seen in reproduction studies in rats and rabbits only at dose levels toxic to dams. At toxic doses (rats at 30 mg/kg/day and rabbits at 100 mg/kg/day), cyclosporine oral solution, USP, was embryo- and fetotoxic as indicated by increased pre- and postnatal mortality and reduced fetal weight together with related skeletal retardations. These doses are 5,000 and 32,000 times greater (normalized to body surface area), respectively, than the daily human dose of one drop (approximately 28 mcL) of 0.05% RESTASIS® twice daily into each eye of a 60 kg person (0.001 mg/kg/day), assuming that the entire dose is absorbed. No evidence of embryofetal toxicity was observed in rats or rabbits receiving cyclosporine at oral doses up to 17 mg/kg/day or 30 mg/kg/day, respectively, during organogenesis. These doses in rats and rabbits are approximately 3,000 and 10,000 times greater (normalized to body surface area), respectively, than the daily human dose.

Offspring of rats receiving a 45 mg/kg/day oral dose of cyclosporine from Day 15 of pregnancy until Day 21 postpartum, a maternally toxic level, exhibited an increase in postnatal mortality; this dose is 7,000 times greater than the daily human topical dose (0.001 mg/kg/day) normalized to body surface area assuming that the entire dose is absorbed. No adverse events were observed at oral doses up to 15 mg/kg/day (2,000 times greater than the daily human dose).

There are no adequate and well-controlled studies of RESTASIS® in pregnant women. RESTASIS® should be administered to a pregnant woman only if clearly needed.

Nursing Mothers

Cyclosporine is known to be excreted in human milk following systemic administration, but excretion in human milk after topical treatment has not been investigated. Although blood concentrations are undetectable after topical administration of RESTASIS® ophthalmic emulsion, caution should be exercised when RESTASIS® is administered to a nursing woman.

Pediatric Use

The safety and efficacy of RESTASIS® ophthalmic emulsion have not been established in pediatric patients below the age of 16.

Geriatric Use

No overall difference in safety or effectiveness has been observed between elderly and younger patients.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis: Systemic carcinogenicity studies were carried out in male and female mice and rats. In the 78-week oral (diet) mouse study, at doses of 1, 4, and 16 mg/kg/day, evidence of a statistically significant trend was found for lymphocytic lymphomas in females, and the incidence of hepatocellular carcinomas in mid-dose males significantly exceeded the control value.

In the 24-month oral (diet) rat study, conducted at 0.5, 2, and 8 mg/kg/day, pancreatic islet cell adenomas significantly exceeded the control rate in the low dose level. The hepatocellular carcinomas and pancreatic islet cell adenomas were not dose related. The low doses in mice and rats are approximately 80 times greater (normalized to body surface area) than the daily human dose of one drop (approximately 28 mcL) of 0.05% RESTASIS® twice daily into each eye of a 60 kg person (0.001 mg/kg/day), assuming that the entire dose is absorbed.

Mutagenesis: Cyclosporine has not been found to be mutagenic/genotoxic in the Ames Test, the V79-HGPRT Test, the micronucleus test in mice and Chinese hamsters, the chromosome-aberration tests in Chinese hamster bone-marrow, the mouse dominant lethal assay, and the DNA-repair test in sperm from treated mice. A study analyzing sister chromatid exchange (SCE) induction by cyclosporine using human lymphocytes *in vitro* gave indication of a positive effect (i.e., induction of SCE).

Impairment of Fertility: No impairment in fertility was demonstrated in studies in male and female rats receiving oral doses of cyclosporine up to 15 mg/kg/day (approximately 2,000 times the human daily dose of 0.001 mg/kg/day normalized to body surface area) for 9 weeks (male) and 2 weeks (female) prior to mating.

PATIENT COUNSELING INFORMATION

Handling the Container

Advise patients to not allow the tip of the vial to touch the eye or any surface, as this may contaminate the emulsion. To avoid the potential for injury to the eye, advise patients to not touch the vial tip to their eye.

Use with Contact Lenses

RESTASIS® should not be administered while wearing contact lenses. Patients with decreased tear production typically should not wear contact lenses. Advise patients that if contact lenses are worn, they should be removed prior to the administration of the emulsion. Lenses may be reinserted 15 minutes following administration of RESTASIS® ophthalmic emulsion.

Administration

Advise patients that the emulsion from one individual single-use vial is to be used immediately after opening for administration to one or both eyes, and the remaining contents should be discarded immediately after administration.

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What to know about a Lip Biopsy

by Vidya Sankar, DMD, MHS



Vidya Sankar, DMD, MHS

The clinical presentation of Sjögren's varies a great deal. While some patients will experience oral dryness and/or eye dryness alone, others may experience other symptoms such as fatigue, malaise, and/or arthralgia (joint pain) that vary in severity. Some may even experience systemic symptoms such as vasculitis or neuropathies. To complicate matters, many of these presenting symptoms are nonspecific and may be seen in various other medical conditions or as side effects of several medications.

Unfortunately, there is no ONE test that can diagnose the disease. Therefore, results from multiple tests are usually evaluated when making a diagnosis and none of these tests are specific to Sjögren's. Tests measuring salivary and lacrimal gland function (salivary and tear flow rates) can be affected by medications you take, other systemic illnesses, caffeine intake, the time of day the tests are obtained, as well as states of dehydration. The most common blood test, anti-SSA autoantibodies, are usually positive in only 30-70% of Sjögren's patients and are not considered totally specific to the disease since they are found in 30% of lupus patients.

When the diagnosis is not clear, tissue studies (biopsy) such as the salivary gland biopsy are extremely helpful in diagnosing the disease. Inflammation and cells that respond to inflammation build up within the exocrine glands (salivary and lacrimal). As inflammation increases, it obliterates and destroys normal functioning gland tissue. If the tissue cannot function or is destroyed, saliva and tears cannot be produced.

You have two pairs of major salivary glands, the

parotid (in front of the ears/cheek region) and submandibular (below the jaws/neck region) glands. Combined, these salivary glands produce about 90% of your saliva. In addition to those major salivary glands, there are about 750 minor salivary glands distributed throughout the mouth. They can be found just about anywhere within the oral cavity but are abundant inside the lips, cheeks and on the palate (roof of the mouth). Although there are so many of these minor glands, they only produce about 10% of total saliva. Biopsying the major salivary glands can be tricky due to the location of nerves and blood vessels within and throughout the glands and cosmetic concerns (biopsies are done through the skin of the face/neck). While the same pathological findings are seen in the lacrimal glands, their proximity to the eye makes it impractical to biopsy these glands. The minor salivary glands are very easy to access, biopsies are done within the mouth so esthetics are not an issue. For these reasons, the minor salivary glands are frequently selected for biopsy.

The minor gland biopsy can be done under local anesthesia (xylocaine) administered directly to the area being biopsied. A small incision is made, less than ½ an inch, and around 4 glands are removed. The site is usually closed with a couple stitches and the procedure is over within 10-15 minutes. Patients are free to resume routine activities immediately but are cautioned about eating/chewing since they might bite their lip and not be aware of it due to the numbness. The numbness usually lasts for a couple hours. Once

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“Top 5” *continued from page 2 ▼*

5. Screening for head and neck emergencies or flares associated with non-extraglandular Sjögren’s

Patients with Sjögren’s whose disease is confined to the salivary glands, eye, head and neck areas occasionally develop complications, which may mandate emergent treatment. These include acute inflammation of the parotid gland (parotitis, or Mikulicz’s syndrome, with either a stone or focus of inflammation, treated with corticosteroids), corneal ulcerations, blocked salivary ducts (affecting the mouth), and dental caries or abscesses. Most Sjögren’s patients see a dentist 2-3 times a year to get their teeth cleaned, and are often frequent return visitors to their otolaryngologist (ENT doctor).

Purchase Dr. Wallace’s talk, “Sjögren’s – Where Are We in Drug Development” from the 2016 SSF National Patient Conference on page 14. In his presentation, Dr. Wallace gives an update on clinical trials and therapies that are in the pipeline for Sjögren’s.

In summary, screening for the five features reviewed above, can prevent or promote early treatment of the overwhelming complications with Sjögren’s. ■

“Dry Skin” *continued from page 1 ▼*

Your dermatologist can be your best resource and may be able to give you samples of products to try. Here are some basic dry skin tips that may help:

- Use gloves when you are using strong soaps or chemicals to clean. One way to get in the habit is to keep a pair of gloves in several areas (i.e. kitchen, bathroom, garage).
- Avoid fabric softeners in the washer and dryer.
- After swimming, make certain that you shower and then immediately use a moisturizer.
- Use warm, not hot, water for bathing and use soap sparingly (shampoo might also be drying to the rest of your body in the shower).
- Take short, warm baths or showers. They do not remove skin oils as completely as hot water.
- Terry robes will dry you gently. Or after the shower, let yourself dry naturally to let the water’s moisture be absorbed by your skin.
- After bathing, apply lotion as soon as possible to seal in moisture.
- Use a humidifier, especially if you have forced-heat, which is especially drying (for Sjögren’s patients, an optimal range of humidity is between 55% and 60% regardless of the ambient temperature).

These tips are from the SSF Patient Education Sheet: Dry Skin by John R. Fenyk, Jr., MD.

Visit www.sjogrens.org to learn more or view the education sheets directly at: <http://www.sjogrens.org/home/about-sjogrens/brochures-and-fact-sheets>. ■

in memoriam

In Memory of Georgie Littlefield

Sandy and Lauren Brown
Marylin Pedgrift

In Memory of Maria Victoria Almazan Reyes

Daniel and Barb Rezabek

In Memory of Helene Larkin

Eulalie Cogswell
Marie and Wes Matthei
Carol Spalding
Eileen Wladyka
Maureen Roche

In Memory of Joyce Judice

McElroy, Quirk and Burch, CPA
Eloise Verret

Alfred and Winona Peveto

In Memory of Linda C Zerby

Joyce and Frank Cignetti

in honor

In Honor of Marie Regas Kaufman

Jennine and Paul Regas

“Lip Biopsy” *continued from page 5 ▼*

the anesthesia wears off, routine over the counter pain medications such as ibuprofen or acetaminophen are sufficient to manage the post-operative pain. The biopsy site heals quickly with little to no scarring. If scars do develop, they are inside of the mouth so it is of little to no esthetic concern. Side effects include minimal post-operative bleeding which is usually controlled by the stitches as well as placing gauze pads with a little pressure. This typically lasts for a few minutes up to an hour. Swelling can occur- reaching its peak 2-3 days after the procedure and then resolves. Infections are rare. Prolonged numbness or tingling in the area has been reported in about 5% of patients. A majority of these patients with prolonged numbness/tingling, regain normal sensations within several weeks to months. A number of medications, both prescription and herbal, may have an impact on bleeding and ability to heal. Therefore, it is important to tell your doctor about them so that the appropriate measures can be taken to minimize these events.

Biopsies should be performed by individuals who are familiar with lip biopsy procedures, this includes Oral Medicine specialists, and certain Oral Surgeons and Otolaryngologists (ENTs). Once the specimens are obtained, the tissue should be sent to Oral Pathologists who are familiar with the specific inflammatory characteristics and patterns associated with Sjögren's for diagnosis.

Although not routine, multiple biopsies have proven to be a useful tool in assessing patient's responses to treatment. Some research studies have looked for changes in the minor salivary glands before and after treatment to determine if certain medications are capable of lowering the inflammation within the glands and if the reduced inflammation is associated with restoration of normal gland function.

The minor gland lip biopsy is a safe procedure and can be instrumental when it comes to diagnosing Sjögren's. Understanding the role of the biopsy in diagnosis and what to expect when undergoing the procedure may help patients seek out physicians when making the determination to have the biopsy. ■

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*PEAK10SKIN was a sponsor for the SSF patient conference in Seattle.



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Ask the SSF Staff

by Kathy Hammitt, SSF Vice President of Medical & Scientific Affairs

Q “I heard that you need a positive lip biopsy result to participate in a Sjögren’s clinical trial. Why is that required?”

A A lip biopsy is frequently required for a patient to participate in a clinical trial for Sjögren’s. The results, however, do not necessarily have to be positive in order to participate if a sufficient number of other tests are positive for Sjögren’s. Eligibility to enroll in a trial depends on the “inclusion criteria” which a person has to meet. In addition, a lip biopsy might be required by a specific trial for assessing the success of a therapy.

All clinical trials for Sjögren’s have to have some way of determining whether a patient definitely has Sjögren’s or not, or the information gained from the trial cannot be proven to be beneficial specifically for Sjögren’s patients. A lip biopsy is still considered the gold standard for diagnosing Sjögren’s, as it is the only objective test available that can demonstrate with a high level of certainty that someone, indeed, has Sjögren’s. As a result, a lip biopsy often is specifically required when screening patients to make sure those entering a clinical trial have the disease.

The inclusion criteria for a trial often simply state that a person must satisfy the rules for a Sjögren’s diagnosis according to an accepted, published set of criteria. To meet these rules, most patients will need to undergo a lip biopsy. However, the procedure isn’t always necessary if the patient meets a majority of other criteria involving positive blood test results and tests demonstrating the presence of dry eye and/or dry mouth. The requirement depends on a specific company’s protocol. The professionals managing the trial can always tell you if a lip biopsy is required.

In addition to being useful for a precise diagnosis, a lip biopsy might be important for determining how well a therapy works. The tissue obtained through a lip biopsy can show microscopic changes with use of a therapy and can be one way to show how a therapy is affecting your disease. In this case, one biopsy will be done before and another after therapy. Sometimes, patients will be given a choice between a lip biopsy and a parotid gland biopsy.

For diagnosis of other diseases or symptoms, people undergo biopsies, for example, of the kidney, esophagus, GI tract, skin, liver, or lymph nodes. Comparatively, the lip biopsy in Sjögren’s is a relatively simple procedure. Ultimately, remember that in order to find a treatment for this devastating disease, clinical trials are critically important. Participating in a successful clinical trial can lead to a new systemic therapy that can reduce the severity of symptoms and prevent complications and deliver a much better quality of life for all Sjögren’s patients!

The Sjögren’s Syndrome Foundation is working hard to ensure that our knowledge and tools for treatment are expanded so that better ways are discovered for diagnosing Sjögren’s and measuring how treatments work. The importance of the lip biopsy could change in the future as new ways of testing become available (such as discovering new biomarkers associated specifically with Sjögren’s or validating new tests such as parotid gland ultrasound). ■

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You Stood Up!

You Stood Up: World Sjögren's Day Raises \$11,483!

World Sjögren's Day was created to commemorate the birthday of Dr. Henrik Sjögren, the Swedish ophthalmologist who discovered the disease in 1933.

This year, on July 23rd and what would have been Dr. Sjögren's 117th birthday, the SSF community came together to recognize advancements made in Sjögren's this past year and raise funds to continue moving the field of Sjögren's forward. We encouraged patients, their family and friends and everyone else touched by Sjögren's to take action by sharing their story.

Thanks to your generosity, we raised an incredible \$11,483 to help advance research and awareness for this debilitating disease in honor of all patients.

Together, we will transform the future of Sjögren's! ■



Dr. Henrik Sjögren

2016 SSF Event Fall Calendar

SEPTEMBER

Cycle for Sjögren's on Sunday, September 18, 2016 in Chico, CA

Sjögren's Comedy Night on Saturday, September 24, 2016 in Harrisburg, PA

OCTOBER

Vermont Trail Run on Saturday, October 8, 2016 in Burlington, VT

Team Sjögren's Denver on Sunday, October 16, 2016 in Denver, CO

Northern Virginia Sip for Sjögren's on Sunday, October 23, 2016 in Herndon, VA

NOVEMBER

Houston Walkabout on Saturday, November 12, 2016 in Houston, TX

If there is already an event in your area and you would like to get involved, or learn about starting one, please visit www.sjogrens.org or contact us at (301) 530-4420 x207



The medications that cause dry mouth, May also be the leading cause of your **Vaginal Dryness**

INTRODUCING
LUVENA®

The Closest
You Can Get to
Natural Moisture

Restorative + Hydrating

No Parabens. No Glycerin.
Just long-lasting soothing comfort
with advanced odor control.

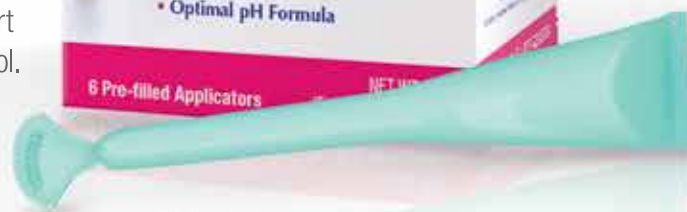


From the Creators of

biotene® **

THE #1
RECOMMENDED
BRAND FOR
DRY MOUTH

Luvena® utilizes similar
enzyme technology
as in Biotene®.



Natural, Innovative & Effective

Compare Ingredients	Luvena® 6 CT	RepHresh® Vaginal Gel	Replens® Vaginal Moisturizer 14 CT
Lactoferrin	✓ YES	NO	NO
Cranberry Extract	✓ YES	NO	NO
Natural Enzyme Protection	✓ YES	NO	NO
Paraben Free	✓ YES	NO	NO
Glycerin Free	✓ YES	NO	NO

*RepHresh and Replens are registered trademarks of Church & Dwight

**Biotene® is trademark owned by GlaxoSmithKline



Most women will experience dryness...
NEW products NOW available to help.

For information call: 1-877-522-5333 | www.luvencare.com



NeutraSal® is a prescription strength oral rinse for dry mouth that has been proven to help improve a range of painful dry mouth symptoms, such as

- Difficulty eating, drinking, and swallowing
- Ability to speak
- Sore tongue and taste disorders
- Burning or stinging sensations in the throat
- Difficulty wearing dentures

Its supersaturated calcium phosphate formulation mimics your natural saliva to help repair and protect oral tissues, reduce bacteria levels to help prevent cavities, and help restore a healthy mouth.

NeutraSal® is easy to use 2 to 10 times a day, as needed, with single-use packets that dissolve in water. It has no added flavors, no anticipated side effects, and no known interactions with medicinal or other products.

For more information, visit www.neutrasal.com.

NeutraSal® is a registered trademark of Valeant Pharmaceuticals International, Inc., or its affiliates.
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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. **(CFC #10603)**

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(c3) organization and qualify for most payroll

deduction campaigns. If they need more information, please contact the Foundation at 800-475-6473 and ask for Elizabeth Trocchio.

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:





SSF in Action!



In July, the SSF sat down with leadership from the U.S. Food and Drug Administration (FDA) to talk about our shared commitment of getting safe, effective, new therapeutics developed to treat Sjögren's. Steven Taylor, SSF CEO, Kathy Hammitt, SSF VP of Scientific and Medical Affairs, Frederick Vivino, MD, FACR, Chief of Rheumatology, Presbyterian Medical Center, University of Pennsylvania, and Sarah Martin, MS, PhD, SSF Director of Advocacy and Scientific Affairs, represented the SSF at the meeting. Specifically, the meeting focused on discussion of the opportunities and challenges in designing clinical trials for Sjögren's and how to ensure that those trials have the best possible chance of success.

The meeting was extremely productive and the SSF learned a great deal about what the FDA will expect from clinical trial sponsors as well as clinical endpoints. During the meeting, SSF leadership gained new appreciation for FDA's willingness to be flexible with regard to clinical effectiveness measures as long as those measures were both appropriate to the disease/therapeutic and rigorously executed. Furthermore, the FDA was keenly interested in continuing to work with SSF to ensure that the patient voice is heard, captured and considered.

This meeting was a great step forward but the SSF is looking forward to continued dialogue with the FDA

as the Foundation continues to represent all Sjögren's patients! Moving forward, the SSF will continue to bring all relevant stakeholders together to work with the FDA. Already, SSF held a conference call of our Clinical Trials Consortium, composed of corporate partners and key Sjögren's opinion leaders, to discuss the outcomes of the FDA meeting. ■



Steven Taylor, Kathy Hammitt, and Dr. Frederick Vivino

Missed the 2016 National Patient Conference?



Get all the vital information you need on an audio CD!

Audio CDs of the most popular talks from our 2016 National Patient Conference in Seattle, WA will be available soon.

The most popular talks from the 2016 National Patient Conference held in Seattle, Washington, are available for purchase as audio CDs. Each talk is 30-40 minutes long and comes with the handouts used by the presenter.

Buy just the talks you want to hear or purchase the whole set!

	Non-Member	Member	Qty.	Total
Sjögren's Overview by Timothy B. Niewold, MD	\$30	\$18		
Oral Manifestations of Sjögren's by Ava J. Wu, DDS	\$30	\$18		
Dry Skin and Dermatological Issues by John R. Fenyk, Jr., MD	\$30	\$18		
An Inside Look at Sjögren's and Gluten-Free Diets by Keith Wilkinson, NMD	\$30	\$18		
Ocular Manifestations of Sjögren's by Majid Moshirfar, MD	\$30	\$18		
Sjögren's - Where Are We in Drug Development? by Daniel J. Wallace, MD	\$30	\$18		
Gynecological Issues with Sjögren's by Rita Melkonian, MD	\$30	\$18		
Examining Sjögren's - Case by Case by Nancy Carteron, MD	\$30	\$18		
Fatigue and Sjögren's by Donald E. Thomas, Jr., MD	\$30	\$18		
Maryland Residents add 6% sales tax				
Shipping and Handling: U.S. Mail: \$5 for first item + \$3 for each additional item Canada: \$14 for first item + \$3 for each additional item Overseas: \$22 for first item + \$3 for each additional item				
Total Amount Due				

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 U.S. bank, net of all bank charges) payable to SSF.

☐ MasterCard ☐ VISA ☐ Discover ☐ AmEx Card Number _____

Exp. Date _____ Security Code _____ Signature _____

Coordinate a **Bold Blue Day** for Sjögren's!

What is Bold Blue Day?

Imagine your colleagues or classmates trading in their tailored slacks or dresses for a day in **blue jeans** or **bold blue** to raise vital funds for Sjögren's research and awareness.

Ask your company or your school (even your kid's school) to consider doing a dress down day for the SSF.

How does it work?

Each person choosing to dress down would donate a suggested amount to the SSF as their fee for participating. Some companies suggest \$5 while others companies/schools let each person decide how much they want to donate.

What if your company doesn't ever allow jeans?

Then just have a BOLD BLUE DAY – where on a certain day everyone chooses to wear their favorite BOLD BLUE outfit! Then collect donations for the SSF that day as well.

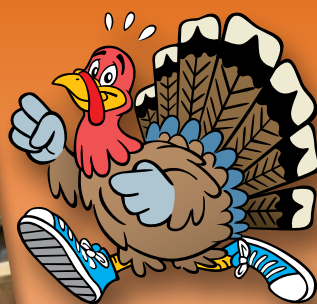
To receive more information or have a "Bold Blue Day" kit sent to you, contact Bess Atkinson at (800) 475-6473 ext. 218 or batkinson@sjogrens.org to receive your "Bold Blue Day" kit.

Sjögren's
Syndrome
Foundation



The Moisture Seekers
Sjögren's Syndrome Foundation Inc.
6707 Democracy Blvd., Ste 325
Bethesda, MD 20817
Phone: 800-475-6473
Fax: 301-530-4415

If you would like to receive this newsletter but are not currently an SSF Member, please contact us! 800-475-6473



Team Sjögren's

Team Sjögren's Goes Turkey!

This Thanksgiving, we hope you will consider participating in your community Turkey Trot as member of Team Sjögren's!

What a great way to start your day of giving thanks – by purchasing a Team Sjögren's Turkey Trot Kit and walking or running with others in your area, increasing awareness for Sjögren's and helping raise crucial funds for Sjögren's research.

We hope you consider creating your own Turkey Trot by asking family and friends to join you for a morning walk on Thanksgiving in your neighborhood while wearing your Team Sjögren's T-shirts! You can also find a local Turkey Trot by visiting www.active.com or in your local newspaper.

Order your Team Sjögren's Turkey Trot-Kit by calling 800-475-6473 or online at www.sjogrens.org. Additional T-shirts can be added to a Kit by calling the SSF office.



A Single Kit Includes:

- SSF Awareness Bracelet
- Team Sjögren's T-shirt, with Turkey Trot logo on the front!
- Certificate of Participation
- "What is Sjögren's?" Brochure
- SSF Reusable Shopping Bag

Price: \$30 plus shipping and handling



A Two-Person Kit Includes:

- 2 SSF Awareness Bracelets
- 2 Team Sjögren's T-shirts, with Turkey Trot logo on the front!
- 2 Certificates of Participation
- 2 "What is Sjögren's?" Brochures
- 2 SSF Reusable Shopping Bags
- 1 SSF Picnic/ Stadium Blanket

Price: \$55 plus shipping and handling