

The Moisture Seekers

Sjögren's
Syndrome
SF
Foundation

www.sjogrens.org

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The Questions You Asked and the Answers You Need



Q *What does it mean to remineralize your teeth? I have heard a great deal about Recaldent and Xylitol. Can you explain what these two products help with?*

A Saliva plays a huge role in the remineralization of teeth. Saliva has the naturally occurring minerals calcium and phosphate that contribute to the remineralization process and to keeping the pH at neutral. When saliva in the mouth is reduced, the teeth are vulnerable to longer durations of demineralization. If you suffer from dry mouth, it is imperative for your teeth to have additional sources of calcium and phosphate. Because the enamel of the tooth does not have a blood supply, the tooth cannot absorb calcium from the inside out. It has to have a topical application to absorb from the outside in in order for the tooth to remineralize.

Remineralization is the restoring (putting back) of minerals into the enamel of the tooth. This is the opposite of demineralization, which is the removal of minerals from your teeth. Demineralization happens when the tooth is exposed to acid. This happens when the pH in the mouth drops below 5.5. The mouth is under a constant acid attack during the drinking of acidic beverages (sodas 2.3 acidity). Also, there are other sources of acids in our diets, such as foods that are good for you (orange juice 3.6, apple juice 3.4) and some that are not so good for you (sour candies... Now and Laters 1.6). Keeping the pH at 7 is not an easy task, but our saliva does a great job neutralizing the mouth.

There are products on the market that can help out the saliva during these devastating events. Recaldent, which is found in MI Paste from GC America, and Trident gum from Cadbury Adams will replace the minerals that are removed during the demineralization process and start the remineralizing process. Recaldent is

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like vitamins for your teeth. Ask your dental professional about other products that also are available.

Xylitol is a "tooth friendly" sugar. The bacteria in our mouth, strep mutans, like sugar. They eat it and the waste they produce is an acid, which is what demineralizes the enamel. Xylitol is a 5-carbon sugar that the bacteria in the plaque do not like. So, instead of eating it and producing an acid, the bacteria just spit it back out; therefore, no acid is produced. Without the sugar to sustain the bacteria, it reduces the bacterial count – less bacteria, less acid, and less demineralization.

Darren Simpson, DDS

Please discuss the long-term use of Plaquenil and possible vision damage.

A Retinal toxicity of Plaquenil (hydroxychloroquine) may manifest itself with subtle disturbances of the retinal pigment epithelium which eventually may lead to complete destruction of the macula in the form of bull's-eye maculopathy. Several risk factors may increase the likelihood of retinal toxicity from Plaquenil such as age of greater than 60 years, daily dose more than 6.5 mg/kg; use of the drug more than five years, obesity, preexisting retinal disease and renal or liver failure.

Early detection of the maculopathy is of critical importance in order to discontinue Plaquenil to stop or slow retinal damage. Unfortunately, clinically evident early structural changes can be subtle and usually preceded by abnormalities in functional tests such as visual field examination, multifocal electroretinography (mfERG), fundus autofluorescence (FA) imaging, and optical coherence tomography. Recent findings suggest that Plaquenil toxicity can develop among patients who are taking the drug at a daily dose lower than the suggested "safe" dose and/or have been on Plaquenil for less than five years. Unfortunately, cessation of Plaquenil intake may not be a remedy since, frequently, patients will develop objective evidence of progression despite discontinuation of the drug. Thus, the possibility of toxicity should not be disregarded, and close monitoring of the ocular findings is required.

Tongalp H. Tezel, MD

What are some routine blood tests that Sjögren's patients should be having and how often?

A For the majority of patients with established Sjögren's syndrome, routine blood tests are not necessary. Laboratory testing is important to monitor those Sjögren's patients who are taking certain medications, who have extra-glandular involvement (such as associated diseases of the liver, kidney, or blood), or who are at higher risk of lymphoma.

The medications for Sjögren's patients who require routine blood monitoring include NSAIDs (CBC, electrolytes, and creatinine, every 6-12 months during chronic NSAID therapy), prednisone and other corticosteroids (blood glucose,

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I'm not shy about
speaking my mind...

I was putting artificial tears in my
eyes time after time, all day long

So I asked my doctor about RESTASIS®

RESTASIS® (Cyclosporine Ophthalmic Emulsion) 0.05% helps increase your eyes' natural ability to produce tears, which may be reduced by inflammation due to Chronic Dry Eye. RESTASIS® did not increase tear production in patients using anti-inflammatory eye drops or tear duct plugs.

Important Safety Information:

RESTASIS® Ophthalmic Emulsion should not be used by patients with active eye infections and has not been studied in patients with a history of herpes viral infections of the eye. RESTASIS® should not be used while wearing contact lenses. If contact lenses are worn, they should be removed prior to use. The most common side effect is a temporary burning sensation. Other side effects include eye redness, discharge, watery eyes, eye pain, foreign body sensation, itching, stinging, and blurred vision.

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 see next page for important product information.

Ask your doctor if RESTASIS® is right for you.
Go to www.restasis30.com or call
1-877-432-2227 for a free information kit. **Find out more**
about a \$20 rebate offer! See next page for details.

 Available by prescription only.
Restasis
(Cyclosporine Ophthalmic Emulsion) 0.05%

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Leader in Dry Eye Care

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RESTASIS®

(cyclosporine ophthalmic emulsion) 0.05%
Sterile, Preservative-Free

INDICATIONS AND USAGE

RESTASIS® ophthalmic emulsion is indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.

CONTRAINDICATIONS

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

WARNING

RESTASIS® ophthalmic emulsion has not been studied in patients with a history of herpes keratitis.

PRECAUTIONS

General: For ophthalmic use only.

Information for Patients

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.

Do not allow the tip of the vial to touch the eye or any surface, as this may contaminate the emulsion.

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.

Carcinogenesis, Mutagenesis, and Impairment of Fertility

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 1000 and 500 times greater, respectively, than the daily human dose of one drop (28 µL) of 0.05% RESTASIS® BID into each eye of a 60 kg person (0.001 mg/kg/day), assuming that the entire dose is absorbed.

Cyclosporine has not been found 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).

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 15,000 times the human daily dose of 0.001 mg/kg/day) for 9 weeks (male) and 2 weeks (female) prior to mating.

Pregnancy-Teratogenic Effects

Pregnancy category C.

Teratogenic Effects: No evidence of teratogenicity was observed in rats or rabbits receiving oral doses of cyclosporine up to 300 mg/kg/day during organogenesis. These doses in rats and rabbits are approximately 300,000 times greater than the daily human dose of one drop (28 µL) 0.05% RESTASIS® BID into each eye of a 60 kg person (0.001 mg/kg/day), assuming that the entire dose is absorbed.

Non-Teratogenic Effects: 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 30,000 and 100,000 times greater, respectively than the daily human dose of one-drop (28 µL) of 0.05% RESTASIS® BID 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 17,000 and 30,000 times greater, 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 post partum, a maternally toxic level, exhibited an increase in postnatal mortality; this dose is 45,000 times greater than the daily human topical dose, 0.001 mg/kg/day, assuming that the entire dose is absorbed. No adverse events were observed at oral doses up to 15 mg/kg/day (15,000 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.

ADVERSE REACTIONS

The most common adverse event following the use of RESTASIS® was ocular burning (17%).

Other events 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).

Rx Only



Based on package insert 71876US14B Revised February 2010

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U.S. Patent 5,474,979

Made in the U.S.A.

Fill a RESTASIS® Ophthalmic Emulsion prescription and we'll send you a check for \$20!*

It's easy to get your \$20 rebate for RESTASIS® Ophthalmic Emulsion. Just fill out this information and mail.

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1. Have your prescription for RESTASIS® filled at your pharmacy.
2. Circle your out-of-pocket purchase price on the receipt.
3. Mail this certificate, along with your original pharmacy receipt (proof of purchase), to **Allergan RESTASIS® Ophthalmic Emulsion \$20 Rebate Program, P.O. Box 6513, West Caldwell, NJ 07007.**

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For more information, please visit our Web site, www.restasis30.com.

***RESTASIS® Rebate Terms and Conditions:** To receive a rebate for the amount of your prescription co-pay (up to \$20), enclose this certificate and the ORIGINAL pharmacy receipt in an envelope and mail to Allergan RESTASIS® Ophthalmic Emulsion \$20 Rebate Program, P.O. Box 6513, West Caldwell, NJ 07007. Please allow 8 weeks for receipt of rebate check. Receipts prior to September 30, 2011 will not be accepted. One rebate per consumer. Duplicates will not be accepted. See rebate certificate for expiration date. **Eligibility: Offer not valid for prescriptions reimbursed or paid under Medicare, Medicaid, or any similar federal or state healthcare program including any state medical or pharmaceutical assistance programs. Void in the following state(s) if any third-party payer reimburses you or pays for any part of the prescription price: Massachusetts. Offer void where prohibited by law, taxed, or restricted. Amount of rebate not to exceed \$20 or co-pay, whichever is less.** This certificate may not be reproduced and must accompany your request for a rebate. Offer good only for one prescription of RESTASIS® Ophthalmic Emulsion and only in the USA and Puerto Rico. Allergan, Inc. reserves the right to rescind, revoke, and amend this offer without notice. You are responsible for reporting receipt of a rebate to any private insurer that pays for, or reimburses you for, any part of the prescription filled, using this certificate.

You Look Marvelous!



Thank you to everyone who has already sent in a picture for our “Where Were You Seen: Casting Call.” Keep them coming! We need more pictures of you wearing your Sjögren’s attire! We have seen pictures of people heading to the gym, carrying groceries in their SSF bags, walking their pets and even one patient on a cruise!

With that said, many of you have asked us where you can purchase more Sjögren’s merchandise and we have the answer to your question. The SSF is now partnering with Café Press to provide the items you’ve requested. We are now offering:

Clothing: Polos, tank tops, sweatshirts (to name a few)

Drinkware

Kindle/ iPad sleeves

Beach bags

Jewelry

Pet items

And much more!

So now you can be seen at a BBQ with friends in a Sjögren’s apron or go on vacation with a Sjögren’s beach bag. Just purchase your items by visiting www.cafepress.com/sjogrens-syndromefoundation or by going to our Shop for Sjögren’s webpage on www.sjogrens.org. Purchasing items from Café Press is an easy way to help support the SSF while also raising awareness for Sjögren’s. With April being Sjögren’s Awareness Month, there’s no better time to stock up on Sjögren’s merchandise.

Awareness never looked so good, and we can’t wait to see your pictures so we can print them in upcoming issues of *The Moisture Seekers*! Remember to email your pictures to tms@sjogrens.org or mail them to the Foundation office.

Increasing awareness takes all kinds of activities, so start by showing off your Sjögren’s pride!

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when first initiated), and immunosuppressive agents—such as methotrexate, azathioprine, mycophenolate mofetil (CBC and liver function tests every 8-12 weeks and more frequently when the treatment is initiated). Patients on cyclophosphamide may need more frequent monitoring of their CBC and periodic urinalyses. In general, routine blood tests are not necessary for Sjögren's patients taking hydroxychloroquine (Plaquenil®), pilocarpine (Salagen®), cevimeline (Evxac®), or topical cyclosporine (Restasis).

Certain forms of extra-glandular disease in Sjögren's syndrome require routine blood testing to monitor the activity of the organ involvement and/or the benefits of treatment and the potential side effects of medications. Prominent examples would include interstitial nephritis with renal tubular acidosis (which can be associated with electrolyte abnormalities), biliary cirrhosis, autoimmune hepatitis, anemia, and leucopenia. Some forms of extra-glandular disease are treated with immunosuppressive agents and routine blood tests are required to monitor the therapy.

A minority of Sjögren's patients have a type of disease which is inherently associated with a higher risk of lymphoma development. These patients are almost always identified at the time of their initial evaluation for Sjögren's syndrome and have key clinical and laboratory features, including palpable purpura (a vasculitic rash of the lower extremities), low levels of serum complement, monoclonal proteins, or cryoglobulins. In such patients, routine blood tests are warranted every 12 months or less to look for changes that might indicate the interval development of lymphoma, including blood counts, protein electrophoreses, immunoglobulin quantitation, free light chain ratio, and complement levels.

Alan Baer, MD

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

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

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

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

Gary N. Foulks, MD, FACS

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

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

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

Frederick B. Vivino, MD, FRCR

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

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

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

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Numoisyn Liquid

Prescribing Information

Ingredients: Water, sorbitol, linseed (flaxseed) extract, *Chondrus crispus*, methylparaben, sodium benzoate, potassium sorbate, dipotassium phosphate, propylparaben.

How Supplied: 30 mL per bottle or 300 mL per bottle.

Therapeutic Group: Numoisyn Liquid is an oral solution formulated for the relief of chronic and temporary xerostomia (dry mouth), which may be a result of disease, medication, oncology therapy, stress, or aging.

Indications: Numoisyn Liquid is indicated for the treatment of symptoms of dry mouth. Numoisyn Liquid relieves the symptoms of dry mouth by enhancing swallowing, improving speech mechanics, and lubricating the oral cavity like natural saliva. Numoisyn Liquid may be used to replace natural saliva when salivary glands are damaged or not functioning. The viscosity is similar to that of natural saliva.

Contraindications: Numoisyn Liquid are contraindicated in patients with a known history of hypersensitivity to any of the ingredients.

Special Precautions for Use: As Numoisyn Liquid contains linseed (flaxseed) extract, patients with irritable bowel syndrome or diverticular disease or those on a high linseed diet may experience abdominal discomfort.

Warning: Federal law restricts Numoisyn Liquid to sale by, or on the order of, a physician or properly licensed practitioner.

Interactions: There are no known interactions between Numoisyn Liquid and any medicinal or other products.

Directions for Use: Shake bottle well. Take 2 mL (about 1/2 teaspoon) of Numoisyn Liquid and rinse around in the mouth before swallowing. Use as needed.

Side Effects: Patients may experience difficulty in swallowing, altered speech, and changes in taste. If side effects persist or become severe, patients should contact a physician.

Storage: Store at room temperature. Do not refrigerate. Use within 3 months of first opening. KEEP OUT OF REACH OF CHILDREN.

Please Note: Numoisyn Liquid is translucent and may contain some natural particles that do not affect the quality of the product.

Manufactured in Italy under license from
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Godalming, Surrey GU7 1XW UK

Distributed by
ALIGN Pharmaceuticals, LLC
Berkeley Heights, NJ 07922 USA

www.alignpharma.com

Numoisyn™
Liquid

Numoisyn Lozenges

Prescribing Information

Ingredients: Sorbitol (0.3 g per lozenge), polyethylene glycol, malic acid, sodium citrate, calcium phosphate dibasic, hydrogenated cottonseed oil, citric acid, magnesium stearate, and silicon dioxide.

Pharmaceutical Form: Oral lozenge

Contents: 100 lozenges per bottle. Net weight of 40 g (0.4 g per lozenge).

Therapeutic Group: Numoisyn Lozenges are oral lozenges formulated to promote lubrication of oral mucosa that may be dry due to a variety of circumstances, including medication, chemotherapy or radiotherapy, Sjögren's syndrome, or oral inflammation.

Indications: Numoisyn Lozenges are indicated for the treatment of xerostomia (dry mouth). Numoisyn Lozenges provide temporary relief of dry mouth due to damaged salivary function. Numoisyn Lozenges are formulated to support the natural protection of teeth provided by saliva so that no damage occurs to teeth with repeated use of the lozenges.

Contraindications: Numoisyn Lozenges are contraindicated in patients with fructose intolerance or a known history of hypersensitivity to any of the ingredients.

Warning: Federal law restricts Numoisyn Lozenges to sale by, or on the order of, a physician or properly licensed practitioner.

Interactions: There are no known interactions between Numoisyn Lozenges and any medicinal or other products.

Directions for Use: Let one Numoisyn Lozenge dissolve slowly in the mouth when needed. To obtain optimal effect, move the lozenge around in the mouth. Repeat as necessary. Do not exceed 16 lozenges in 24 hours.

Side Effects: Excessive consumption can cause minor digestive problems.

Storage: Store at room temperature. KEEP OUT OF REACH OF CHILDREN.

Overdose: No overdoses have been reported to date.

Manufactured in Italy under license from
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Lozenges



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NEW

NeutraSal[®] Sjögren's Syndrome Support Kit

Containing:

- **NeutraSal[®]**
- **Omega-3 with Vitamin E Supplement*
for Dry Eyes and Dry Mouth comfort**
- **Dry Mouth Gum with Xylitol**

*Compare to the ingredients in Thera Tears Nutrition (Advanced Vision Research, Inc.)

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The symptoms of Sjögren's Syndrome can have devastating effects. Oral dryness can result in severe and chronic dental decay, fissures, infections, and difficulty in speaking and swallowing.

Introducing NeutraSal[®] (Supersaturated Calcium Phosphate Rinse)

What is NeutraSal[®]

NeutraSal[®] is an advanced electrolyte solution indicated in the treatment of dry mouth (xerostomia) in patients with Sjögren's Syndrome. NeutraSal[®] consists of single use packets of dissolving powders that when mixed with water creates an oral rinse supersaturated with calcium, phosphate and bicarbonate ions.

- Calcium and phosphate ions have been shown to aid in the the prevention of dental caries (cavities) and promote the remineralization of the teeth in normal saliva
- Sodium bicarbonate ions reduce the acidity of the saliva in the mouth and break up accumulating mucus
- The pH of NeutraSal[®] is similar to normal saliva which may protect the mouth against potential opportunistic fungal (oral thrush) and bacterial infections
- Clinically proven to relieve the symptoms of dry mouth in Sjögren's Syndrome patients with no reported side effects or drug to drug interactions

NO PATIENT LEFT BEHIND PROGRAM

The No Patient Left Behind Program is designed to provide access to NeutraSal[®] treatment for all patients regardless of their insurance coverage and includes no out-of-pocket costs for patients. NeutraSal[®] is a prescription only product. Ask your physician.

INVADO
PHARMACEUTICALS

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yeast and other infections are ruled out, your doctor should be looking for signs of inflammation to the tissues in the area and try to determine a reason for the inflammation.

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

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

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

Lynn M. Petruzzi, RN, MSN



I frequently experience an intensely painful burning and pin-prick sensation on my tongue. Is this related to Sjögren's? Is there any treatment?

A burning sensation is a common oral complication of Sjögren's syndrome. The cause of a burning sensation/pin-prick sensation is frequently related to decreased salivary flow associated with Sjögren's. Lower salivary flow will lead to decreased lubrication and subsequently more mucosal (i.e. tissues in the mouth such as cheeks, gums and tongue) irritation and burning – especially with the tongue. As saliva has natural properties to fight fungal/yeast infections, a decrease in salivary flow also can lead to an increased risk of oral fungal infections. An active oral fungal infection can manifest as mucosal burning. Other causes of oral burning may be related to vitamin deficiencies, oral allergies or autoimmune-related oral lesions.

Successful treatment of oral burning requires the correct diagnosis of the underlying cause of the burning. Increasing salivary flow will benefit burning from poor lubrication, and appropriate antifungal therapy will provide relief for an active fungal infection. Appropriate management can also be provided to supplement vitamins, eliminate allergens or treat autoimmune oral lesions.

Michael T. Brennan DDS, MHS



Can NSAIDs be dangerous for Sjögren's patients?

A The prolonged use of higher doses of non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen,

naproxen, celecoxib, and meloxicam, is associated with an increased risk of adverse gastrointestinal, renal, and cardiovascular side effects, particularly in individuals over the age of 65 years. The gastrointestinal side effects include the development of ulcers, primarily in the stomach, and associated ulcer complications, such as bleeding, perforation, and occasionally obstruction. The renal side effects include electrolyte disturbances (particularly increased serum potassium levels), impairment of kidney function and, rarely, necrosis of the renal papillae. The cardiovascular side effects include the rare occurrence of heart attacks and strokes. These side effects are more likely to occur in individuals with certain associated medical conditions, such as a history of peptic ulcer disease, heart disease, blood clots, chronic kidney disease, or ongoing treatment with anticoagulants or corticosteroids.

A physician must take particular care in prescribing NSAIDs for Sjögren's patients who are over the age of 65 years or who have any of the risk factors mentioned above. Of particular relevance to Sjögren's syndrome would be those patients who are taking regular doses of corticosteroids or who have any form of Sjögren's-related kidney disease (interstitial nephritis or glomerulonephritis). In such Sjögren's patients, NSAIDs can be dangerous.

Fortunately, many Sjögren's patients do not have the risk factors mentioned above and are candidates for NSAIDs as a treatment for their arthritis or other painful conditions. In order to minimize the risk of NSAID therapy in any patient, there are certain guidelines to follow. The NSAID dose should be the lowest effective therapeutic dose. Your physician should prescribe a NSAID that is less likely to cause gastrointestinal complications if chronic therapy is anticipated. Some examples would include nabumetone, meloxicam, and low-dose celecoxib, naproxen or ibuprofen. The NSAID should be taken with food. Finally, a proton pump inhibitor can reduce the risk of gastrointestinal ulceration, but this strategy should only be employed in patients with known risk factors for NSAID-induced ulcers and is best employed for short-term and not long-term NSAID therapy.

Alan Baer, MD



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

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

Philip C. Fox, DDS

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"Q&A" continued from page 9 ▼

Q Is a Vegan Diet beneficial for people with Sjögren's?

An Answer from a nutritionist...

A A vegan diet excludes any animal products. A raw diet limits cooking foods over 116 degrees. You may be wondering if this is the diet prescription to help you. Should you eliminate animal products? Do you have to avoid cooking your food to reap the optimal nutrition value?

Not necessarily. Each person suffering from Sjögren's syndrome (or any medical condition) should learn to individualize their treatment plan, including diet modifications. Learning to incorporate foods that are well tolerated and minimize foods that exacerbate symptoms of Sjögren's is the overall nutrition goal.

What works for others may be very different from what works for you. For example, raw foods are often more difficult to chew and digest. A person with dry mouth and digestive issues may have difficulty tolerating a plan that is vegan and raw. In that case, the raw/vegan diet is not the best approach to nourishment.

Another example of how nutrition should be individualized? Not every person with Sjögren's syndrome needs to avoid gluten. Only those with celiac disease (or a clear-cut worsening of symptoms) should eliminate gluten in the diet.

Nutrition strategies for the management of Sjögren's syndrome are consistent with an anti-inflammatory food pattern. This includes foods rich in phytonutrients such as fruits, vegetables, whole grains, beans, nuts, seeds, spices and tea. Phytonutrients are powerful nutrients found in plant-based foods that are thought to offer our cells protection from many diseases and conditions such as heart disease, cancer and autoimmune conditions. The balanced vegan diet (raw or not) has a heavy emphasis on phytonutrient rich foods and is, therefore, a good example of an anti-inflammatory pattern. That said, it is not the only type of diet that fits on the spectrum of an anti-inflammatory eating pattern.

We are in the preliminary stages of learning if animal proteins are harmful to those with autoimmune conditions. It appears that large portions of animal protein such as red meat and dairy and little intake of plant-based foods is the real problem and can influence your condition in a negative way. The typical American diet is rich in animal protein and lacks fruits, vegetables and other plant-based powerhouses.

A simple shift towards a more plant-based diet with less reliance on meat and dairy is likely sound advice for those with Sjögren's syndrome. The diet does not need to be exclusively vegan or raw to be healthful.

The Harvard School of Public Health's Healthy Eating Plate is an excellent visual of how to shift the plate to include more plant-based foods with a balance of lean proteins, healthful fats and adequate fluid.

Another new diet may be popular tomorrow. Your goal should be to discuss your symptoms and eating pattern with your physician. A registered dietitian (RD) can help you individualize and balance your eating pattern based on your specific needs.

<http://www.hsph.harvard.edu/nutritionsource/healthy-eating-plate/>

Tara A. Mardigan, MS, MPH, RD
Senior Clinical Nutritionist,

Dana-Farber Cancer Institute, Boston, Massachusetts

An Answer from a rheumatologist...

A First, what is a Vegan diet? Basically, it is a vegetarian diet (no meat) plus no animal-related foods (no eggs, milk, cheese, fish, fowl). Protein is derived from beans (especially soybeans...tofu, tempeh*), grains, and nuts. Many choose this diet for environmental philosophical reasons. They want to reduce their "carbon footprint," in addition to avoiding potentially harmful substances (estrogens, antibiotics) that can end up in industrialized foods.

I found no data that a Vegan diet is more beneficial than a Mediterranean diet (largely vegetarian) in autoimmune diseases such as Sjögren's. As a physician who sees a large number of Sjögren's and other autoimmune disease patients, I have some concern that a strict Vegan diet may not be as anti-inflammatory or anti-oxidant as current data suggests is beneficial for autoimmunity and cancer. Foods such as cold-water fish (salmon) would be excluded, which is high in the anti-oxidant/anti-inflammatory Omega-3 essential fatty acids. For those who choose a Vegan diet, microalgae oil (instead of salmon), calcium-fortified foods (in place of dairy), Vitamin D, B12, and Iron are needed for a balanced diet.

Generally, anti-inflammatory diets are higher protein, complex carbohydrates, higher Omega-3, anti-oxidant (bright colored fruits and veggies), certain spices, such as turmeric, curcumin, ginger, garlic, cinnamon, and licorice, and lower wheat (gluten). Occasionally, patients will have "flares" after dairy or food allergies, and they should minimize these food triggers.

Furthermore, going "organic" may be of value when trying to heal from an autoimmune disease. These foods are supposedly freer of chemicals, such as antibiotics, fertilizers, and pesticides. The higher cost of many purchased organic foods may limit access. In my opinion a balanced diet along with some form of exercise and restorative sleep is the optimal formula for healing from Sjögren's.

Six Dietary Recommendations for Autoimmune Disease:

1. Avoid animal fat, except for oily fish.
2. Favor a predominantly vegetarian diet.
3. Consume whole grains, fruits, and vegetables that are rich in vitamins E and C, especially bright-colored ones, such as broccoli, red and green sweet peppers, and spinach.

continued page 14 ▼

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 dose medical supervision to patients with controlled asthma, chronic bronchitis, or chronic obstructive pulmonary disease.

Ocular:

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

PRECAUTIONS

General:

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

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

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

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

Drug Interactions:

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

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

Carcinogenesis, Mutagenesis and Impairment of Fertility:

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

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

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

Pregnancy:

Pregnancy Category C.

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

Nursing Mothers:

It is not known whether this drug is secreted in human milk. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from EVOXAC®, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use:

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use:

Although clinical studies of cevimeline included subjects over the age of 65, the numbers were not sufficient to determine whether they respond differently from younger subjects. Special care should be exercised when cevimeline treatment is initiated in an elderly patient, considering the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy in the elderly.

ADVERSE REACTIONS

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

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

Adverse Event	Cevimeline	Placebo
	30 mg (tid) n=533	(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	Placebo	Adverse Event	Cevimeline	Placebo
	30 mg (tid) n=533	(tid) n=164		30 mg (tid) n=533	(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, hypertonia, peripheral edema, chest pain, myalgia, fever, anorexia, eye pain, earache, dry mouth, vertigo, salivary gland pain, pruritus, influenza-like symptoms, eye infection, post-operative pain, vaginitis, skin disorder, depression, hiccup, hyporeflexia, infection, fungal infection, sialadenitis, otitis media, erythematous rash, neurodermatitis, edema, salivary gland enlargement, allergy, gastroesophageal reflux, eye abnormality, migraine, tooth disorder, epistaxis, flatulence, toothache, ulcerative stomatitis, anemia, hypoesthesia, cystitis, leg cramps, abscess, eruption, 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 part 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, leukopenia, 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 oxaloacetate 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, hyperlipidemia, hypertriglyceridemia, hyperuricemia, hypoglycemia, hypokalemia, hyponatremia, thirst

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

Neoplasms: basal cell carcinoma, squamous carcinoma

Nervous Disorders: carpal tunnel syndrome, coma, abnormal coordination, dysesthesia, dyskinesia, dysphonia, aggravated multiple sclerosis, involuntary muscle contractions, neuralgia, neuropathy, paresthesia, speech disorder, agitation, confusion, depersonalization, aggravated depression, abnormal dreaming, emotional lability, manic reaction, paranoia, 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 erythematous rash, lupus erythematous 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, stranguary, urethral disorder, abnormal urine, urinary incontinence, decreased urine flow, pyuria

In one subject with lupus erythematous 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 ALT 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, hypoesthesia, paralysis, abnormal sexual function, enlarged abdomen, change in bowel habits, gum hyperplasia, sensitivity 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, impotency, neurosis, paranoid reaction, personality disorder, hyperhemoglobinemia, apnea, atelectasis, yawning, oliguria, urinary retention, distended vein, lymphocytosis

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

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

MANAGEMENT OF OVERDOSE

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

Ⓡ Only

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

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 **in memoriam**

In Memory of Anne Kilbride
Marjorie Leeds

In Memory of Barbara Loper
Marsha Atcheson
Reggie Gibson & Jamie Jones

In Memory of Gilbert Feinstein
Barbara Feinstein

In Memory of Irene Seaner
Mildred Izzi
David & Kathleen Morais
Lorraine Ritchie
Kenneth & Dorothy Rowland

In Memory of Jane W. Coffey
Felissa Lashley

In Memory of Joy Cox
Dr. Beth Pascaner Boger
Colonial Heights Pharmacy, Inc.
Dean & Charlotte Cox
Jim & Pat Downs
Carol & Alan Giles
Danny, Robin & Quade Hilton
Deanna Mauldin
Miller Perry Elementary
William & Jerri Sunderland
The Keep Moving Class, Johnson City Wellness Center

In Memory of Lee Berris
Naomi & Neil Arnold

In Memory of Michael Decker's Mother
Sandy & Bob Leon

 **in honor**

In Honor of Kathy Morgan
Liz Eysink

In Honor of Mr. & Mrs. Larry Levin's Anniversary
Hannah & David Kaplan



New Edition and Fundamental Reading

The Sjögren's Book – Fourth Edition
Edited by Daniel J. Wallace, MD

The **NEW 2011 Edition** of the Sjögren's handbook has been completely revised and expanded with **ALL NEW** chapters and the latest information on Sjögren's!

This book can be purchased online at
www.sjogrens.org/ssfstore
*or by contacting the Sjögren's
Syndrome Foundation office at*

800-475-6473.



sip for
Sjögren's
a fine water
tasting event

**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.

"Q&A" continued from page 10 ▼

4. When adding oils to foods, use canola, soy, safflower, sunflower, and olive oils.
5. Take a well-balanced all-inclusive vitamin and mineral supplement that includes 100 percent of the RDA for each of the vitamins and minerals.
6. If advised by your physician, look for an antioxidant supplement containing vitamins E and C, carotenoids, and selenium; a bone-strengthening supplement containing calcium, magnesium, and vitamin D; an omega-3 fatty acids supplement containing EPA, DHA, and vitamin E; and a B-vitamin supplement that is particularly rich in vitamin B6, folic acid and vitamin B12.

Nancy Carteron, MD, FACP

* tempeh – a whole soybean product high in protein, fiber, and vitamins

Additional information on Vegan diet: http://www.medicinenet.com/vegetarian_and_vegan_diet/article.htm



Donate Your Old Vehicle

Sjögren's Syndrome Foundation

Call us today for more information.

800-475-6473

April Breakthrough Bullet: How are people being diagnosed with Sjögren's?

One of the main difficulties with diagnosing Sjögren's is that symptoms vary from person to person. Often patients will visit their dentist for dry mouth or excessive tooth decay and then their primary physician for joint pain and fatigue. This makes it difficult for both the patient and physician to put the symptoms together.

As we continue on the road of achieving our breakthrough goal of shortening the time to diagnose Sjögren's by 50% in 5 years, it is important to first identify the main reasons why people go to the doctor and seek a diagnosis.

In a recent survey of over 4,000 Sjögren's patients, it was discovered that the four main reasons patients sought a diagnosis (in order) were:

- Dry eyes
- Dry mouth
- Fatigue
- Joint pain

While we know Sjögren's is much more than just the hallmark symptoms of dry eyes and dry mouth, it is important to note that they are the two top symptoms that caused patients to seek a diagnosis.

What is also important to note is that in the same survey,

dry eyes and dry mouth were ranked #1 and #2 for symptoms patients currently still experience after diagnosis:

Common Symptoms Experienced by Patients Post Diagnosis were:

- 92% Dry eyes
- 91% Dry mouth
- 86% Sleep disruption

This is why, it is imperative that we reach out to dentists, dental hygienists, ophthalmologists, optometrists and rheumatologists with information about Sjögren's and its hallmark symptoms. These are the physicians who are on the front lines and can help speed up a diagnosis of Sjögren's.

So remember, the Foundation offers "Dry Eyes," "Dry Mouth" and "What is Sjögren's Syndrome?" brochures to all medical offices, free of charge. We hope you will consider taking some of them to your next doctor visit! Sign up to be an Awareness Ambassador or help us spread the word about Sjögren's by distributing brochures!

Just call our office and request some brochures and we will mail them to you. Or have your doctor's office contact us or sign-up online for brochures. Visit www.sjogrens.org or call us at 800-475-6473.

Research Grants

Applications for the Sjögren's Syndrome Foundation's 2012 Research Grants are in and we are thrilled to announce that the number of applications has nearly doubled from last year and the quality of candidates with exciting and creative proposals exceeds all previous years.

Having so many researchers take an interest in starting or continuing their careers in Sjögren's gives hope to finding more treatment options and a cure but also signifies the increased value that the medical community is finding in conducting Sjögren's research.

Thanks to the generosity of our members, supporters and corporate partners, we are able to be the premiere organization in Sjögren's research funding, but now we need your help more than ever before to grow our research program and match the increase of innovative projects being proposed by talented researchers.

This year the SSF will have to turn away more applicants than ever before, which means turning away the chance of chance of reaching a Sjögren's research breakthrough. It is always difficult to turn away talented researchers due to lack of funds since our goal is to encourage them to pursue a career in Sjögren's research.

The SSF research program goal is to provide funds for the first stage of promising ideas that can then continue to develop with grants from larger institutions, such as NIH. The more innovative projects we fund, the more Sjögren's will be noticed by these larger institutions.

These talented applicants are the reason we continue to increase the number of awareness events and fundraising activities to carry out our mission of not only educating and creating awareness of Sjögren's but also encouraging vital research of this debilitating disease.

Applications are currently being reviewed by the SSF Research Review Committee, composed of experts in Sjögren's, and the awardees will be announced later this spring – but we need your help!!!

Please consider making a donation for research today by returning the form below or contacting the Sjögren's Syndrome Foundation. If you'd like to make a stock donation or have another way of supporting research, please contact us at 800-475-6473. Also, if you know of a family or private foundation that would consider supporting our research program, please let us know!



Together we will find a cure!

RESEARCH – OUR HOPE FOR THE FUTURE

The Sjögren's Syndrome Foundation's Research Campaign

Yes, I would like to help fund the best and most innovative research into Sjögren's syndrome.

Please accept my tax-deductible gift: \$100 \$250 \$500 \$1,000 \$2,500 \$5,000 Other _____

Name: _____

Address: _____

Phone: _____ Email Address: _____

My donation is attached (check made payable to the Sjögren's Syndrome Foundation) or

Credit Card (MC/Visa/AMEX/Discover) #: _____ Exp. Date: _____ CC Code: _____

Signature: _____

Complete this pledge sheet with your information and return it to the Sjögren's Syndrome Foundation.
 Mail to: SSF, c/o BB&T Bank, PO Box 890612, Charlotte, NC 28289-0612 or Fax to: 301-530-4415.
 Or visit www.sjogrens.org/donate and make a donation restricted to research.

The Moisture Seekers

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

Phone: 800-475-6473
Fax: 301-530-4415

Join in the fun! 2012 SSF Special Event Calendar

The SSF is very excited for all of our events coming this Spring. Look at our special event calendar below to see if there is a *Walkabout* or *Sip for Sjögren's* coming to your area.

Visit www.sjogrens.org or
contact the SSF office to
learn more about our events!

May

- 5** ***Philadelphia Walkabout & Health Fair***
Philadelphia Zoo, Philadelphia, Pennsylvania
- 9** ***Sip for Sjögren's - Harrisburg***
West Shore Country Club, Camp Hill, Pennsylvania
- 12** ***Dallas/Fort Worth Walkabout & Health Fair***
Grapevine Mills Mall, Grapevine, Texas

June

- 2** ***Kansas City Walkabout***
Independence Center, Independence, Missouri
- 3** ***Northeast Ohio Walkabout***
Oak Grove Picnic Area at Brecksville Reservation,
Brecksville, Ohio
- 9** ***Greater Washington Region Walkabout***
Lake Fairfax Park, Reston, Virginia
- 16** ***Denver Area Walkabout***
Denver Zoo, Denver, Colorado

sip for
Sjögren's
a fine water
tasting event

Sjögren's Walkabout

