Clinical trials already show promise for sodium oxybate in the treatment of fibromyalgia. Courageous new work suggests that the drug may also have applications for myofascial pain.

Xyrem

Why Me? Why Now?

By Devin J. Starlanyl

In November 2008, Jazz Pharmaceuticals announced that the first Phase III clinical trial of Xyrem (sodium oxybate)* in patients with fibromyalgia (FM) showed significant reduction in pain and fatigue and improved daily function. I started on Xyrem in late August, in spite of 12 interactive conditions that included fibromyalgia, chronic myofascial pain (CMP), small airway disease, and obstructive sleep apnea (OSA). I had already tried two of the newest approved FM medications, with terrible consequences. Each time, symptoms crept up as dosage slowly increased. The last increase of the last medication caused tremors, twitching, and total loss of rapid eye movement (REM) sleep, the stage of sleep when dreaming occurs.

In 2003, monthly research for my website had uncovered a study indicating sodium oxybate could restore deep sleep in FM patients.[5] Xyrem had also been used to secure deep stage sleep for patients with narcolepsy, a genetic sleep disorder that includes disrupted night sleep, daytime sleep episodes, and other symptoms. Xyrem is not yet approved for FM, but the first Phase III clinical study indicated it significantly improved FM symptoms and is generally well-tolerated at 4.5 and 6.0 gm a night.[3]

My previous sleep study had shown no stage 3 or 4 sleep even with the continuous positive airway pressure (CPAP) apparatus that I use for obstructive sleep apnea**.** Since I was losing function daily without sleep, I thought a Xyrem trial was indicated, with careful precautions and starting at a low dose. My primary care physician (PCP) agreed.

*The active ingredient in Xyrem oral solution is gamma-hydroxybutarate (GHB), a metabolite of GABA. GABA is a neurotransmitter that can help reduce central nervous system (CNS) pain and relax muscles.

With new medication, I take careful notes. Following a long tradition of scientists and medical researchers, and with the help of my PCP and a support network, I morphed into lab rat mode.

A seriously curious and observant lab rat with a scientific and medical background can be exceedingly useful. However, becoming a lab rat means more than donning a set of (for me, well-used) whiskers and *very* tiny lab coat and taking extra precautions around my Siamese. It means perseverance while running through the maze of trying a new medication and dedication to the process of monitoring what happens while trying to figure out why. I've never before worked with a pharmaceutical company so comprehensive in its instruction and monitoring of patients. Even so, they were unfamiliar with several of my conditions.

I was informed that Xyrem could cause serious side effects, including trouble breathing while asleep, confusion, abnormal thinking, depression, loss of consciousness, sleep walking, suicidal thoughts, psychosis, and death. My husband was heading off on a long business trip. I was losing ground daily. I needed action before I slid into a state wherein I could not advocate nor care for myself. With the help of my medical team and a network which included my church, I set up a phone tree and other support. I made as many preparations as I could, gearing up to blaze trails. Although I had done my homework, it turned out that I was unprepared because what happened was totally unexpected.

Before you read the next segment, you need to know that I'm still on Xyrem, and it is doing some amazing things. I believe that what happened to me and what I found is important information for patients with FM, their care providers, and supporters.

Notes from Lab Rat #1

I began cautiously with a starting dose of 2 gm/night, a level that my primary care physician and I agreed was prudent for a patient with my particular medical conditions. The plan was to raise the dose slowly. Since the instructions called for diluting the Xyrem in water, I used the softened well water available at my house. It didn't occur to me at first that the sodium present in softened well water could cause complications when added to the sodium already inherent in Xyrem (sodium oxybate).

The instructions also called for no food after 6 pm; the first dose was scheduled at 10 pm. By 10:15, I was in agony with excruciating pain. I prayed, meditated and tried to figure out what was happening and why. I had neither sleepiness nor dizziness nor breathing difficulties. When I wasn't getting up to urinate (at least every half hour), I stayed on the CPAP. No problem getting to the bathroom. My mind was clear except for pain that filled my universe. My nose ran, and my eyes teared. Every joint screamed. Was the pain due to extreme activation of myofascial trigger points (TrPs) or something else? I was so stunned by pain that I couldn't figure out if it was *all* TrPs or also profound FM amplification and/or some other problem I hadn't yet discerned.

I used numbing gel on mouth TrP areas that I could reach, and that helped. I realized how much the CPAP mask and jaw strap aggravated the TrPs. I did stretching in bed and Chinese Hanxiong energy balancing, and I prayed. I took the next dose at the earliest time I could, hoping for sleep. I also took a lot of notes. By 2:00 am., I was reading. The pain had eased a little over time, relatively speaking, but my muscles were so tight that cool air from the CPAP or turning my head in bed set off spasms. At 8:30 am., after no sleep, I got up.

That next day was bad, with increased pain and muscle cramps. I'd lost fluids and gotten no sleep. I had easy, healthy meals in the freezer yet still had difficulty feeding myself and tending to the cats. Urinary frequency continued throughout most of the day. Pain levels lowered with my regular meds, but only to a "9" on a 1-10 scale. I contacted the folks on my phone tree and the rest of my support system and told them I was hurting but alive.

Fortunately, I have a guardian angel, J.B. Eisinger, who is like a big brother to me and is a superb physician who understands my conditions and me. Unfortunately, he is in France, and I am in New Hampshire. Yet he monitored me through this whole process. I was exceedingly blessed by his care and that of other dear friends who kept tabs on me.

I was better able to prepare for the second night. I put up night lights and did mind work and body work. I took a diuretic to help eliminate excess fluid. I replaced lost minerals. I added more stretching and more t'ai chi, and I put a good book beside the bed. I did a lot of self-therapy with Frequency Specific Microcurrent (FSM) that told me my body was getting rid of wastes and toxins through the liver.

That night, I verified that the pain onslaught was TrP activation. I stretched the CPAP hose and worked some TrPs against the wall with a tennis ball to gently press on or against TrP contraction nodules. I continued with the Xyrem, according to the plan I had developed together with my PCP, slowly raising the dose every night, but I still didn't sleep. My mind was clearer, but my muscles were tighter. My leg muscles contractured so much that when I was on my side the lower part of the calf didn't touch the surface of the bed. I spent a lot of the nights working those muscles with my knees, elbows, and toes.

Due to the long duration of my chronic myofascial pain and the nature of my multiple perpetuating factors, I have hundreds of TrPs in layers in so many muscles. Some pain is more prominent than others. I kept thinking: "People *abused* this drug? *On purpose?"*

To her credit, the Xyrem nurse assigned to me was informative and encouraging. I learned that insomnia was rare but could happen early in therapy. I learned that frequent urination was rare also but could continue the first week, even during the day, as it did. I wasn't thirsty in spite of the fluid loss which

Glossary

Frequency Specific Microcurrent (FSM): A form of electrotherapy pioneered by Carol McMakin, DC, which offers a system of treatment for nerve and muscle conditions using microamperage current and the resonance effects of frequencies on tissues and conditions to create beneficial changes to symptoms and health.

Perpetuating factors: those conditions/stressors that cause a myofascial TrP to remain in place, despite efforts to break it up. Perpetuating factors may occur alone or with others. They may be behavioral (i.e., posture), biochemical (i.e., nutritional inadequacy), or mechanical (i.e., poorly fitting shoes). The concept of perpetuating factors is equally appropriate for FM and other chronic diseases, and FM and TrPs often share metabolic perpetuating factors.

Trigger point (TrP) activation: the process by which latent TrPs (nonpainful but causing weakness and other dysfunction) become generators of pain as well as dysfunction.

made me think that my body was getting rid of something that needed to be gone. (Note: I believe that bed wetting is a common side-effect of Xyrem because insomnia is rare. I didn't sleep, perhaps due to the intense TrP pain, so I was able to get up to urinate and didn't wet the bed.)

After nights without sleep, with medical approval, I started a regimen of Xyrem every other night to prevent more sleep deprivation. The days I didn't take Xyrem, I used my old meds. On those nights I got REM sleep. After a time, I did get a few hours of sleep on Xyrem, including REM, right after the second dose, but the pain was still intense. I did not drive for some time until I was sure it was okay. This meant that I was forced to cancel a lot of needed physical therapy. With inadequate sleep and high pain levels, I just didn't have the focus needed to drive, and there is no nearby public transportation in my area.

Slowly, some "side-effects," such as TrP-patterned numbness in my feet, began to ease or grow more specific. As one area of pain lessened, another started. I began to notice a change in tissue density in some areas. My range of motion (ROM) increased for some muscles. When I saw my massage therapist, my whole body was tight. For weeks I had been getting 8 hours of sleep (on the nights I didn't take Xyrem) out of every 48. My mind was alert and often racing as it tried to accommodate to the changes in my body, but both my body and my mind were exhausted. Sometimes I couldn't even read or follow a TV show. I just stared into space and let my mind try to rebalance.

Despite extensive research, I had read of nothing which resembled what I was experiencing, and the Xyrem nurse and pharmacists hadn't heard of it either. I questioned friends who had tried Xyrem but couldn't tolerate it. They had FM and CMP and had taken Xyrem for restorative sleep. To them, my experience was familiar. I looked at the Xyrem "side-effect" profile more closely to see how many listed items could possibly be caused or contributed to my TrPs. Each night I used myofascial unwinding techniques that John Barnes had taught me at his clinic in Sedona, AZ. (Imagine a useful type of writhing.) I moaned a lot.

How difficult this experimental undertaking would be for a partner/spouse of a patient! All I had to deal with were three ticked-off cats, and they glowered at me. They didn't appreciate the night movement, noise, lights, and toilet flushing. There was also the series of "catly" disappointments when kitchen lights came on during the night, and no treats were forthcoming. There were also thrashing legs and moving pillows, denying them use of the bed for their slumbers.

By the time my husband returned, I didn't need to stretch as much in bed. The pain was still very intense after my first nightly dose of Xyrem, but I could get one hour of helpful, REM-including sleep after the second dose. My myofascial TrP therapist, Justine Jeffrey, confirmed what I expected—that I had a new body. Her therapy was more effective because my body was now responsive. She could palpate multiple huge taut bands and TrP contraction nodules where before they had been covered by dense, tight tissue. The loss of over 10 lbs. of weight was evident. Even the geloid masses covering deep TrPs in my thighs were softening. Xyrem was having dramatic effects on my TrPs, yet it was supposed to be working on the FM.

I had access to a lot of electrotherapy devices including Frequency Specific Microcurrent, ultrasound, and galvanic stimulation. I also had the use of topical carisoprodol (Soma), which helped greatly as the TrPs became accessible, and rectal lidocaine ointment which helped with IBS. Because of my earlier training in and personal experience with chronic myofascial pain, I recognized the TrPs and knew what to do about them. I also had a medical team including a chiropractor, myotherapist, craniosacral therapist, and massage therapist who knew FM and TrPs, and they were all impressed at the changes they saw and felt in my body. When I saw my PCP, he was delighted at my progress and that I had used so little Xyrem. It was like the Xyrem was peeling off the layers of an onion, although I had a lot of layers.

Life was still tough. One Sunday I made it to worship but had to leave early. I was aching, sweating, and feeling toxic and nauseous in the hot, muggy church. When I got home I needed to rest in bed for several hours (a frequent occurrence). I didn't sleep

Glossary

Galvanic stimulation: A form of electrotherapy which uses a steady, direct (unidirectional) current. This current creates an electrical field over an area of treatment which, in turn, is thought to change blood flow in ways that speed healing.

Geloid masses: extremely taut areas of geloid, rubbery or hard, clearly definable dense tissue with palpable margins. They are associated with and cover sensitive TrPs and may be exquisitely painful to touch. [Ref. Starlanyl DJ, Jeffrey JL, Roentsch G et al. 2201-2202. The effect of transdermal T3 (3,3',5-triiodothyronine) on geloid masses found in patients with both fibromyalgia and myofascial pain: double-blinded, N of 1 clinical study. *Myalgies* 2(2):8-18.]

John Barnes, PT: one of the developers of myofascial release techniques used to relieve restrictions in the 3-dimensional fascial network.

at that time. It was as if my brain needed to integrate what was happening. Then I was able to get up and eat. I was sweating a lot, with much hair washing and showering, but my cane was retired, and soon I sent my handicapped parking tag back to the Motor Vehicle Department. By then I began to experience some restorative, deep stage sleep, but only on non-Xyrem nights. The best I was able to manage on Xyrem, at a total of 5 gm in a divided dose, was 4 hours of pain-troubled sleep. The tearing and runny nose eased considerably when I switched to reverse osmosis (RO) water (where water softening is accomplished without adding sodium). Since taking the Xyrem, I no longer required a light blocking mask to sleep, but sound sensitivity remains to this day.

Observations and Theories

Simplistically speaking, I define FM as central sensitization and its resulting metabolic consequences. We know that myofascial TrPs may contribute significantly to central sensitization.[2] Once the CNS is sensitized, the chronic pain state may be maintained with only minimal pain stimuli.[7] FM may be initiated by many different causes. Many patients have more than one initial cause. Usually by the time FM has been diagnosed, there are multiple interacting co-existing conditions that may or may not be diagnosed and treated. Most patients with chronic pain have treatable TrPs which add to the symptom burden. Once FM and resultant biochemical dysfunctions begin to cascade and interact with the biochemical changes brought about by TrPs,[4] Xyrem may be a way to interrupt the abnormal spiraling interactive feedback loop currently experienced by too many chronic pain patients.

My studies have taught me that any trauma sustained throughout life tends to cause substances such as triglycerides, glycogen, calcium, uric acid, melanin, and bilirubin, to accumulate in abnormal quantities in the cells and tissues,[1] often in the ground substance. Ground substance in connective tissue is made up of water, ions, plasma materials, and other infiltrates which exist between the cells and fibers. Metabolic wastes and toxic materials can become trapped here, often in the form of acidic salts. Ground substance can vary in density from barely a gel to a glue. Its constituents profoundly affect tissue density and mobility. Tissue that was once supple may become dense and rigid. The ground substance is the key to myofascial suppleness, and to much else, as nutrients flow through it and wastes are removed through it.

Many patients with FM and CMP have areas of interstitial edema—swelling or accumulation of water and other materials in the ground substance. I believe that the frequent urination in early Xyrem therapy is due to the release of some of this excess fluid and undesirable infiltrates that contribute to tight areas of dense tissue. The liver and kidneys can handle only so much of the biochemical by-products released at once, so when undergoing treatment, it is important to be careful not to overload the detoxification system.

Even before becoming a lab rat who was trying Xyrem, I knew I had certain TrPs even though I couldn't palpate their taut bands or contraction nodules because the tissue around them was either too dense, fibrotic, or calcified. The pain patterns and/or muscle weakness and restricted range of motion (ROM) and other symptoms told me the TrPs were there. For example, peroneus TrPs (in the calf) can cause buckling of the ankle to the outside. I had this on both ankles and knew multiple TrPs were there under tissue that was dense, hard, tight, and stuck to the bone. Now some of these formerly hidden TrPs can be palpated. How many patients are told that they don't have TrPs because of this tissue masking?

Tight or dense tissue can also act as a brace. It may prevent some of the pain at the end of ROM that is typical of many TrPs, but it also restricts movement and creates abnormal muscle compensation. It hurts when that bracing starts to melt, and you begin to stretch muscles that have been restricted for so long. You need to unwind years of tightness slowly and carefully and work to minimize accompanying pain.

Xyrem Side-Effects or Myofascial Trigger Point Activation?

I've had severe muscle contracture from TrPs for over 57 years, and FM too, with a lot of perpetuating factors. I believe that Xyrem — at this stage in my research — is slowly reversing at least some of that damage to my body and mind. Sinusitis, nasopharyngitis, toothaches, ear pain, vertigo, blurred vision, eye swelling, chest pain, gait abnormality, sensation of foreign body, back pain, tennis elbow, sensation of heaviness, muscle tightness, congestion, difficulty breathing, balance disorder, muscular weakness, musculoskeletal stiffness, abnormal coordination, tension headache, migraine, and many other Xyrem side-effects can be caused by TrPs.[6,8] I couldn't ask patients on Xyrem who had complained about a "sensation of heaviness" if that symptom was in the hips, and if so, check them for quadratus

lumborum TrPs. I couldn't access patients who complained of a "sensation of foreign body" and check for TrPs in the longus capitis, longus colli, and medial pterygoid muscles. I could recognize a pattern of possible TrP activations.

I've tried different ways of taking Xyrem so that it would be more user-friendly, meanwhile allowing the healing process to continue. I had been told "Xyrem will cause drowsiness." It never has for me, nor for Lab Rat # 2, whom you will meet below. I also have not had any problem discontinuing it for a time when I needed to allow metabolic detoxification systems to catch up.

February Report

It's now the end of February. I am on a single dose of 1.5 gm Xyrem every night. I take it about an hour and a half before bed. It's all I can tolerate.

I have no idea how long this maze will take to run, nor where it will lead me. I still have 12 serious conditions. Xyrem still causes significant aching right after I take it until the time I can take my usual meds. I've started decreasing those meds and have eliminated one. I am getting some restorative sleep every night and hope that deeper stage sleep will allow my body to normalize many biochemicals that have been out of balance. It took a long time for my body and mind to get where it was, so I need to have patience with the reversal.

I have gastroesophageal reflux disease (GERD) of long duration and it seems to be getting worse again. Has the previous surgery (fundoplication*) I had for GERD failed, or is it Xyrem? I don't know. I'm checking into it. Computer work causes activation of TrPs, as will any repetitious work or immobility, so I have to pace myself carefully. I don't know how much guaifenesin therapy, ta'i chi, and my other tools have affected this process either.

I don't think Xyrem is for everyone, but I believe it holds great promise. Research is now being done on Xyrem and TrPs , and I hope to see some papers for MYOPAIN 2010, the World Congress of the International Myopain Society which will be held in Toledo, Spain. I also hope a way will be found to make this therapy experience more informed for FM and CMP patients, and much less traumatic.

*Fundoplication is surgery for GERD where they wrap the stomach around the esophagus.

Following in the Paw Prints of the Lab Rat

Some of my friends became interested in Xyrem therapy and asked questions that helped with this article. One, my myofascial TrP therapist, Justine Jeffrey, also started Xyrem therapy as Lab Rat #2. Her experience with Xyrem was equally intense and painful, but the TrP activations and effects were different because we are different. Justine has found a dose regimen that is working for her for now, as mine does for me, but we are both open to the changes that are happening and the adjustments we may have to make.

Justine also has some specific advice for those of you with FM and CMP who are contemplating a Xyrem trial:

> I didn't understand the commitment of time required to document and simply "experience" the body's individualized response. I would have rearranged my life in advance to the extent possible. I would not endure the initial phase without having set up the following: a team of supporters; a bodyworker to come to me on retainer for the first month; a driver to get me where I needed to go; someone to help with housework, food preparation, etc.; and a way to arrange a flexible schedule to allow for sleep disturbances, pain management, CNS sensitization, and times when I could not function.
>
> Most of you have a system wherein you try to keep a balance as best as you can, with varying degrees of success. Be prepared to let go of that status quo. It will probably change, and change is difficult. Right now we don't know enough to even guess what those changes might be, but a philosophy of resilience and adaptability is important. Some of these changes may be tough temporarily, but others may be exquisitely life altering (such as the elimination of chronic migraines). You may need to retrain your body to move in different ways. The goal must be to increase function. The challenges can be extreme, but so can the rewards. You may need to stop Xyrem at times and allow your body and brain to integrate changes that are taking place. Eventually, the cost of Xyrem may be far less than medications and therapies that you would have otherwise needed, and you also

avoid the side effects those other medications may require in addition to the stress they may put on your body to metabolize them.

As for me (Lab Rat #1), I encourage those who dropped out of Xyrem therapy due to simple side-effects such as toothaches and ear pain to get TrP assessment and consider trying again at a lesser dose that is carefully titrated. This therapy, in patients with FM and CMP, requires more than determination. Patients must be carefully screened for compliance and ability to self-monitor or be monitored by care providers who understand multiple interactive diagnoses, including myofascial TrPs and FM. They need a support system of friends and helpers, including a medical team who will listen and monitor carefully, especially at first, and adjust dosage and schedule to find what works for them.

Your spouse or partner may not be the best primary caregiver through the initial weeks of this process. The therapy and the stresses it causes may strain a relationship. It's difficult for someone else to understand. If you are alone, you need people who will check on you and with you unless you contact them and tell them you are okay. Needs will vary.

Each of us has a different set of TrPs and symptoms, co-existing conditions, factors which perpetuate our conditions, and a different set of tools. I don't think many people with FM and CMP will be able to continue with Xyrem therapy in spite of trigger point activation unless they can identify what is happening and ask their physician to modify the protocol. To provide maximum success with the Xyrem program, doctors may need to individually titrate the dose to suit each patient's needs. The needs and support therapies would be predicated upon the patient's symptoms and reactions to Xyrem. This will require careful monitoring.

I can't overemphasize the amount of pain I experienced at the beginning. Many who read this are not strangers to pain. However, what I am describing was mind-blinding, both for me and for Justine. Even when I began to think that Xyrem might possibly be a way to unwind these conditions, it took everything I had to swallow each dose. The people I have met with FM and CMP have no lack of courage, but they often lack the support network (including medical team) required. I didn't know what to expect, I wasn't prepared for the TrP activation and my dosage was too high. I have often been told by members of my medical team that I would be in a tertiary care facility if not for my training and tools.

In the best of all possible worlds, we'd have doctors and other care providers who could diagnose and aggressively treat individual myofascial trigger points when they occur and prevent most cases of CMP and FM. We need to revamp medical and dental training and educate our legal and insurance systems. These systems are glaringly broken, so lets do it. It would save a lot of misery and help our strained health care system. We need to work with the world we have and make it better. I think that even some of those tertiary care patients, with trained individualized support and dosage, may someday be able to make it through this maze, but I'm not sure. I'm still working on it myself. —Devin J. Starlanyl

My thanks to Justine Jeffrey and Nye Ffarrabas who helped with this article

References

1) Leahy M, Mock LE III. 1992. Myofascial release technique and mechanical compromise of peripheral nerves of the upper extremity. *Chiro Sports Med* 6(4):139-140.

2) Niddim DM, Chan RC, Lee SH et al. 2008. Central representation of hyperalgesia from myofascial trigger point. *Neuroimage* 39:1299-1306.

3) Russell IJ, Perkins AT, Michalek JE, et al. 2009. Sodium oxybate relieves pain and improves function in fibromyalgia syndrome: a randomized, double-blind, placebo-controlled, multicenter clinical trial. *Arthritis Rheum* 60(1):299-309.

4) Shah JP, Gilliams EA. 2008. Uncovering the biochemical milieu of myofascial trigger points using in vivo microdialysis: an application of muscle pain concepts to myofascial pain syndrome. *J Bodywork Mov Ther 12(4):371-84.*

5) Scharf MB, Baumann M, Berkowitz DV. 2003. The effects of soduim oxybate on clinical symptoms and sleep patterns in patients with fibromyalgia. *J Rheumatol* 30(5):1070-1074.

6) Simons DG, Travell JG, Simons LS. 1999. *Travell and Simons' Myofascial Pain and Dysfunction: The Trigger Point Manual: The Upper Extremities*, Vol I. 2nd ed. Baltimore: Williams and Wilkins.

7) Staud R. 2006. Biology and therapy of fibromyalgia: pain in fibromyalgia syndrome. *Arthritis Res Ther* 8(3):208.

8) Travell JG, Simons DG. 1992. *Myofascial Pain and Dysfunction: The Trigger Point Manual Vol II: The Lower Extremities*. Baltimore: Williams and Wilkins.

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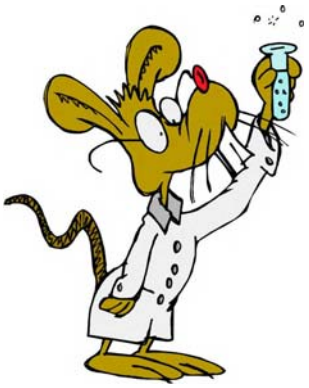

Xyrem: Basics

WHAT IS IT? The active ingredient in Xyrem (sodium oxybate) oral solution is gamma-hydroxybutarate (GHB), a metabolite of GABA. GABA is a neurotransmitter that can help reduce central nervous system (CNS) pain and relax muscles. Xyrem has no known active metabolites, and its by-products, carbon dioxide and water, are removed through respiration. It contains significant sodium. It's approved by the Food and Drug Administration (FDA) for narcolepsy. Xyrem is a controlled substance, listed as habit-forming. GHB has been abused as a street drug and date-rape drug. It can cause serious medical symptoms, including respiratory depression, neuropsychiatric events and death.

HOW IS IT PRESCRIBED? Xyrem comes directly to you from a central pharmacy. You can't get a prescription filled at your local pharmacy. Your doctor must register with the Xyrem pharmacy and also register you for the Xyrem program. Information on this process is available on www.xyrem.com, although the website is exclusively for cataplexic narcolepsy.* Physicians must read their part of the website before they register.

Xyrem is expensive. Some insurance companies pay if you have an approved need. The Xyrem supplier has a reimbursement specialist who will check your coverage and assist you with alternative funding if needed. The pharmacy needs a list of your usual medications and supplements, including over-the counter (OTC) meds such as melatonin and herbs. A pharmacist will call and tell you how many hours you must be off each specific CNS depressant before you can take Xyrem. The pharmacist is used to working with narcolepsy patients and uses standard times based on established clearance values for any CNS depressant medication. Almost all patients who have received Xyrem for narcolepsy were on CNS stimulants to keep them awake during the day. Patients with FM are often on CNS depressants. These may include sleep medications, muscle relaxants and pain medications. You will be able to take approved OTC pain meds. You will be sent detailed instructions from the company, including a video. The material indicates that Xyrem should not be used by those on respiratory depressants or by those who have or have had depression; liver problems; any respiratory problems including sleep apnea, snoring, or lung problems; high blood pressure, heart failure, or kidney problems; or by those who are on a salt-restricted diet; are above age 65, or are in other listed categories. Patients in these categories may be able to take Xyrem, but may require adjustment of dose (titration) and special monitoring during treatment. Each patient is assigned a nurse who will be in telephone contact once (s)he is on Xyrem. The nurse will monitor progress and answer questions.

*Cataplexy includes episodes of generalized sudden loss of muscle tone that can be initiated by strong emotion, even laughter.

ADMINISTRATION OF XYREM: Keep Xyrem at room temperature. You set up two doses in the dosing containers provided, each diluted in about a quarter cup of water. Xyrem is drawn up into a special syringe. It's thick, like molasses. If an air bubble gets into the syringe, it's difficult to measure accurately. One dose is taken at bedtime–from your bed, in case of instant sleepiness— and another is to be taken 2 ½ to 4 hours later. You are to set an alarm to take the second dose 4 hours after the first.

Food directly affects its absorption, so don't eat anything several hours before. I've learned to avoid dinners high in meat and fat, and chew very well. Xyrem is absorbed quickly. Keep it out of reach of children and pets. Avoid activities that require mental alertness for six hours after taking it, and avoid respiratory depressants such as alcohol.

Common side-effects listed are nausea, dizziness, headache, vomiting, sleepiness, and bed-wetting, but the list of side-effects on the insert is long and, to me, very thought-provoking. They don't tell you that you need to add a flavor agent to cover the taste. The agent must not have caffeine, sugar (food blocks Xyrem absorption), or sodium. Logic and experience tell me that includes softened water. Xyrem contains a lot of sodium. I also avoid products with aspertame and coloring agents. I'm using a color-free, sodium- and sweetener-free powdered drink mix.