

PREVIEW

Mind/Body Techniques Can Lead to More Effective Pain Management

Relaxation, hypnosis, meditation, conversational strategies, and other techniques can be a welcome supplement to more traditional approaches to pain management.

"Participants can expect to get a completely new understanding of mind/body medicine, and specifically a new understanding about hypnosis," says Michael Ellner, CHt, MSH— who will present "Mind/Body Techniques: Expanding the Scope of Your Practice" at PAINWeek 2010 today with Daniel Cleary, CHt. Simply describing what they'll discuss as "hypnosis" limits the content of what they'll be sharing, Ellner said. "Dan and I teach meditative approaches—straightforward relaxation, conversational approaches. There are many ways to describe hypnosis, and many people describe it in ways that intentionally avoid the word 'hypnosis,' because it has a lot of baggage. We're giving people various options as to how they communicate to their patients, and the goal is to make everyone attending a better communicator."

Ellner feels that mind/body techniques for relieving chronic pain should be considered a necessary supplement to all pain management strategies for three reasons: 1) available medications don't work for everybody; 2) being able to help someone lower their medication dose because they don't need as much relief is better for everybody involved; and 3) even when medication is effective, in some cases, it loses effectiveness over time or requires doses that come with complications.

"We see ourselves as a supplement to pain management to give people the ability to cope in ways that require less medication," explains Ellner. "We're not against medication; we think everybody should have it and that the pain practitioner should be the one who makes decisions regarding medication. But we know that patients who are better able to cope and/or have a sense of control require less medication. We know people who feel better and have less stress heal more effectively. So, our goal is to help doctors integrate this into their medical practices. We're not saying that every doctor should become a hypnotist or must do these techniques. What we're saying is that there is an adjunct professional standing by to come in and help through referral or actually even directly work with patients in your practice."

Ellner also points out that many things that physicians say are, unintentionally, "weapons of mass destruction." For instance, he says "When a doctor says to a patient, 'Nothing can be done,' that's a life sentence, that is a terrible thing to say. But by adding, 'and I'll do everything I can to help you' gives that person a reprieve, some hope."

He offers the use of the word "positive" as another way that healthcare professionals, without realizing it, can affect patient care. "We live in a culture where everyone is encouraged to strive for positive results," he says. "And then when people get the worst possible news in their life—'your test was positive for cancer,' 'your test was positive for AIDS'—that jades the word; that changes the word dramatically, and that creates a lot of inner conflict because for the first time, they're getting the worst possible news and the word 'positive' now has a very serious negative effect in their lives. And then their pain doctors tell them to think positive, feel positive, try to be positive, try to act positive. And you might as well beat them with a stick." Ellner hopes to remind physicians that test results use to be given as "reactive" or "non-reactive," adding that these words don't have the emotional load that comes with "positive" and "negative." The simple use of a specific word can provoke "a huge amount of pain," he notes. "And it's unconscious pain; the person doesn't know why

they're confused, angry, and disturbed. But there's a deep-felt inner conflict because the words have very different meanings now."

During the session, Ellner and Cleary intend to show attendees various language techniques that allow them to meet the requirements of informed consent. "In order for a doctor to create the space for medical disability payments, they have to give you an MMI (maximal medical improvement)," Ellner notes. "But they should be aware of the additional implications and take a couple of minutes to let a person know that, 'Although this is the best we could do at the moment, you're designed to heal over time. And we're not saying that things can't turn around. This is a snapshot; it'll enable you to get disability or worker's comp payments. It's not written in stone.' The most important thing a person in a chronic situation has is hope. You don't want the person to go home and jump out of a window."

A key point the speakers hope to convey to attendees, according to Ellner, is that "you don't have to say to a person, 'You're getting sleepy, tired, drowsy, blah blah blah' to be an effective conversational hypnotist. There's no communication that takes place between a patient and a doctor that doesn't have a hypnotic implication. Because they're doctors, because of the prestige, because of the perceived expertise, they are one of the most powerful hypnotists. We just want them to use it more skillfully. And none of these things are part of a doctor's education or training."

Many times, medical hypnotists are seen as a last resort for patients who are in pain, explains Ellner. "Now that they're at the end of their rope, they're trying to find some kind of help. We want to get in at the beginning of the road. We believe that can change the outcomes considerably, by just getting people in mindsets that promote wellbeing."

Ellner and Cleary also plan to help physicians distinguish between suffering and pain. "Pain is the mechanical signal, but every signal is mediated in the mind and brain," continues Ellner. "But that mediation determines the person's experience. That mediation is a result of that patient's stress level at a given time, expectations, beliefs, and basic coping skills and abilities. A person can get a signal, and react 'Oh my god, it's the end of the world. I can't cope,' or they could get a signal and still be able to function pretty effectively. The same signal. What matters in terms of suffering is how a person unconsciously reacts to the signal." Ellner believes that every physician attending PAINWeek 2010 can influence that unconscious reaction if they're aware of it. "They don't have to be hypnotists to be really effective at helping their patients with conversational hypnosis," he adds.

The information provided in this session isn't generally available to physicians, as it isn't part of most training or education, which is why Ellner says PAINWeek 2010 attendees need to attend this session. "It will make them more effective as pain practitioners," he says. "We're helping them round out their ability to deal with patients. Keep in mind that effective communication should be required as part of informed consent. We're helping them communicate more effectively—rapport building; when a patient and a doctor earn a rapport, you can bet that the patient is more likely to be compliant."

Every communication a physician has with a patient



"We're not against medication; we think everybody should have it and that the pain practitioner should be the one who makes decisions regarding medication."

can promote anxiety and fear, or relaxation and a sense of control, says Ellner, adding that one the biggest issues pain patients have is not the pain itself, but a lack of control. That lack of control can be worse than physical pain. "What we're looking to do is give people a sense of belief that they do have some level of control, and they do," he continues. "We can help these people go into states of mind, states of being, that are calm and peaceful; that changes a painful experience."

It is terrible that pain management is often presented to the patient as all or nothing, Ellner says. "The doctor writes a prescription, the patient comes back, and the doctor by law is required to get a calibration of the pain. 'Are you still in pain?' says the doctor. 'Yes,' says the patient. It's almost as if they view the treatment as a failure and increase the dosage or change this or that. But really, this person might have experienced some level of relief, and that's very important for them to understand. With my clients, something as small as 10% or 15% relief might be the difference in enjoying their children, the freedom to enjoy a meal, or create the space to make love with a partner. If doctors talk to their patients and begin to look for any kind of improvement and work from there, it is much more helpful to the patient."

The ultimate goal of Ellner and Cleary's session is to inform physicians that professionals exist who are trained and qualified to assist their pain patients as a supplement to what they offer. "A doctor won't recommend a hypnotist if he's not aware that medical hypnotists can help," Ellner adds. "There's a referral service for certified hypnotists who are trained to help assist people in pain, the International Medical and Dental Hypnotherapy Association."

In its fourth year, the presentation by Ellner and Cleary has consistently been one of the favorite offerings at PAINWeek as one of the most exciting, fun, and practical programs.

Your Words Have the Power to Take Away the Pain

Clinicians in all settings can teach their patients to use relaxation, meditation, hypnosis, guided imagery, and other techniques that utilize the mind-body connection to achieve relief from chronic pain conditions. The key for providers is to build a good rapport with their patients.

Daniel F. Cleary and Michael B. Ellner, Cht, MSH, began their presentation, titled "Introduction to Mind/Body Techniques That Relieve Chronic Pain," by asking the audience to repeat the phrases "I feel good," "I feel great," and "You are great" to illustrate the relaxing effect of self-affirmation and demonstrate the power of language and the effect it can have on patients' state of mind.

Cleary reminded attendees that "the mind-body connection is an amazing interaction that has been known for thousands of years." It is only recently that science has finally caught up to tradition. Now, there is growing evidence to support what "everybody has always known intuitively: when patients feel better, they heal better," Cleary said. "The benefits of guided self-help modalities in addressing pain relief have been documented for years. Evidence suggests that these adjunctive approaches have the potential to improve every aspect of living or working with painful conditions or diseases."

Effective treatment for pain starts with establishing a good rapport with the patient and being cognizant of the fact that "you're not dealing with a disease; you're dealing with a person," said Cleary. He also reminded the audience that all medical professionals have "hypnotic relationships" with their patients in that "their words are very powerful and can be effective tools for healing." But, he warned, language can also be destructive and present barriers to effective care if providers are not paying attention to how they are presenting information. Cleary said that when speaking with patients, it is important for clinicians to remind them that "they are not the diagnosis; they are still the same individual they were before tests came back positive."

Pain changes the way a patient's brain is processing their experiences, affecting everything from their experience of the pain itself to their activities of daily living. When people are dealing with chronic conditions, it affects every aspect of their life because the pain is in control. Cleary said that chronic pain "takes over a person's life. They live in its shadow and forget the things they enjoy and that give them pleasure. Changing any aspect of the patient's perception of their pain changes their experience of that pain. Changing their experience returns a sense of control. Even 10% relief can bring 100% improvement in the patient's life."

Cleary described pain as "a set of signals that our brain tells us how to respond to" and said that "patients' perception of their pain is their experience

of that pain signal." Therefore, the goal for clinicians who are treating patients suffering from chronic pain is to "take the suffering out of these painful conditions even if you are powerless to change the cause of these signals."

When these pain signals "are no longer accurate, pa-

tients can learn to bypass the response. Meditation and self-hypnosis are powerful ways to bypass the natural reaction to these 'mistaken' signals. The best way to teach your patients these approaches is to learn and practice them in your own life. When we learn and practice some form of

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Qutenza® is indicated for the management of neuropathic pain associated with postherpetic neuralgia.

IMPORTANT SAFETY INFORMATION
Only physicians or healthcare professionals under the close supervision of a physician are to administer Qutenza®.

Contraindications: None.

Warnings and Precautions:

- Do not use on face or scalp.
- Aerosolization of capsaicin can occur and inhalation may result in coughing or sneezing.
- If skin not intended to be treated comes into contact with Qutenza®, clean area using Cleansing Gel.
- Patients may experience substantial procedural pain. Prepare to treat pain with local cooling (such as a cold pack) and/or appropriate analgesic medication.
- Transient increases in blood pressure may occur during and shortly after the Qutenza® treatment. In clinical trials, blood pressure changes were associated with treatment-related increases in pain. Monitor blood pressure and provide adequate support for treatment-related pain. Patients with unstable or poorly controlled hypertension or a recent history of cardiovascular or cerebrovascular events may be at an increased risk of adverse cardiovascular effects. Consider these factors prior to initiating Qutenza® treatment.

Adverse Reactions: In clinical trials, serious adverse reactions included application-associated pain and increase in blood pressure. The most common adverse reactions (≥5% and greater than control) were application-site erythema, application-site pain, application-site pruritus, and application-site papules.

Please see brief summary of Prescribing Information on adjacent page.

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meditation or self-hypnosis, we become experts in relating the benefits of these approaches to patients," Ellner said.

Ellner also noted that the biggest obstacle with chronic pain is learned helplessness and hopelessness. He also noted that it's common with chronic pain patients that "everything they've done up to that point hasn't worked," so they often come to the office visit "expecting that whatever you are going to do will also not work. They'll do anything to get relief from their pain."

A key part of providing that relief involves utilizing the mind-body connection to promote healing. "You need to capture your patients' attention and use the power of

language to engage their imagination in pain relief," said Ellner. He told the audience that as medical professionals, they are the "authority on whatever the patient has come to you to address. You have their attention." Providers can capitalize on that to teach patients mind-body techniques that can accelerate or utilize the body's natural healing powers in ways that will benefit or create conditions for optimum health.

These techniques can include hypnosis, breathing and relaxation, and guided imagery exercises. "Any clinician can learn the skills needed to help patients use guided imagery and develop their creative self-help skills. You don't have to be a hypnosis professional or certified hyp-

notist to use imagery to help alleviate patients' pain." Helping patients raise what Ellner referred to as their "hypnotic IQ" starts with talking to them about their pain and listening to their descriptions of their pain. Even this simple step utilizes the mind-body connection to promote pain relief because when patients are asked to describe their pain, "they begin to dissociate from it by becoming observers," Ellner said. He recommended that providers ask patients to describe their pain experience using the five primary senses: vision, hearing, touch, taste, and smell. Providers should also guide patients by suggesting imagery they can use to visualize and describe their pain. "Ask them to think about it as a red-hot ball, and then ask them to think about it becoming smaller and changing color to cooler shades," said Ellner. He reminded the audience that "imagination and memory have great influence over your physiology. Remembering or visualizing pleasant or happy images produces endorphins" that promote pain relief.

Cleary said that even a small amount of pain relief can greatly improve patients' lives. He described what he calls his "10% solution" that starts by asking patients about the effect pain has on their lives and the activities of daily living that their pain impacts or prevents them from doing. "Then I ask them about prior efforts at pain control, what worked and what didn't. Then I create within their minds the expectation of successful pain relief by asking how great an impact a 10% reduction in their pain would have on their lives." Then he has the patients focus on their breathing. "When we breathe more deeply, we get more oxygen in the blood and the muscles begin to relax," he said. This simple technique (basically counting down 3-2-1 and taking a deep breath) is powerful and effective because it exceeds the expectations of patients who may have grown accustomed to failing at their efforts at pain relief. "Now you have their attention and they're back in control over their pain," said Cleary.

It's all about creating the expectation of success, said Cleary. "Talk to patients about what is possible and what will work." Clinicians should use positive and proactive language. "You don't want to create the expectation that 'this is going to hurt,' because if you tell them it'll hurt, it will. And never use negative phrases like 'You are going to have to learn to live with the pain.'"

The bottom line, said Ellner, is that when you use these techniques to help your patients be more effective, they'll heal better. He reminded the audience that another way to accomplish this is to take a lighthearted approach when talking to patients about their pain. "Don't forget: 'seriosity' killed the cat. Helping patients lighten up their encounter with you will improve their experience immensely," he said. If clinicians can remember the power and impact of the language that they use and incorporate into their practice guided imagery, relaxation, and other techniques that leverage the mind-body connection to promote healing, Ellner and Cleary said that they can break the negative feedback cycle of pain leading to tension and stress leading to more pain, and help patients regain control over their pain and their lives.

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the skills
needed to
help patients
use guided
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creative
self-help skills**

Qutenza[®] (capsaicin) 8% patch

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BRIEF SUMMARY OF PRESCRIBING INFORMATION
(For complete prescribing information please see package insert.)

DESCRIPTION

Qutenza (capsaicin) 8% patch contains capsaicin in a localized dermal delivery system. The capsaicin in Qutenza is a synthetic equivalent of the naturally occurring compound found in chili peppers.

INDICATIONS AND USAGE

Qutenza is indicated for the management of neuropathic pain associated with postherpetic neuralgia.

WARNINGS AND PRECAUTIONS

Eye and Mucous Membrane Exposure: Do not apply Qutenza to the face or scalp to avoid risk of exposure to the eyes or mucous membranes.

Aerosolization of Capsaicin: Aerosolization of capsaicin can occur upon rapid removal of Qutenza patches. Therefore, remove Qutenza patches gently and slowly by rolling the adhesive side inward. If irritation of eyes or airways occurs, remove the affected individual from the vicinity of Qutenza. Flush eyes and mucous membranes with cool water. Inhalation of airborne capsaicin can result in coughing or sneezing. Provide supportive medical care if shortness of breath develops.

Unintended Skin Exposure: If skin not intended to be treated comes in contact with Qutenza, apply Cleansing Gel for one minute and wipe off with dry gauze. After the Cleansing Gel has been wiped off, wash the area with soap and water.

Application-Associated Pain: Even following use of a local anesthetic prior to administration of Qutenza, patients may experience substantial procedural pain. Prepare to treat acute pain during and following the application procedure with local cooling (such as an ice pack) and/or appropriate analgesic medication, such as opioids. Opioids may affect the ability to perform potentially hazardous activities such as driving or operating machinery.

Increase in Blood Pressure: In clinical trials, increases in blood pressure occurred during or shortly after exposure to Qutenza. The changes averaged less than 10 mm Hg, although some patients had greater increases and these changes lasted for approximately two hours after patch removal. Increases in blood pressure were unrelated to the pretreatment blood pressure but were related to treatment-related increases in pain. Monitor blood pressure during the treatment and provide adequate support for treatment-related pain.

Patients with unstable or poorly controlled hypertension, a recent history of cardiovascular or cerebrovascular events may be at an increased risk of adverse cardiovascular effects. Consider these factors prior to initiating Qutenza treatment.

ADVERSE REACTIONS

The following serious adverse reactions are discussed in Warnings and Precautions: Application-Associated Pain and Increase in Blood Pressure.

Clinical Trials Experience: Across all controlled and uncontrolled trials, more than 1,600 patients have received Qutenza. A total of 394 patients received more than one treatment application and 274 patients were followed for 48 weeks or longer. In controlled clinical studies, 98% of patients completed $\geq 90\%$ of the intended patch application duration. Among patients treated with Qutenza, 1% discontinued prematurely due to an adverse event.

Controlled Clinical Studies: Common Adverse Reactions: adverse reactions occurring in $\geq 5\%$ of patients in the Qutenza group and at an incidence greater than in the control group were application-site erythema, application-site pain, application-site pruritus and application-site papules.

Table 1 summarizes all adverse reactions, regardless of causality, occurring in $\geq 1\%$ of patients with postherpetic neuralgia in the Qutenza group for which the incidence was greater than in the control group. The majority of application-site reactions were transient and self-limited. Transient increases in pain were commonly observed on the day of treatment in patients treated with Qutenza. Pain increases occurring during patch application usually began to resolve after patch removal. On average, pain scores returned to baseline by the end of the treatment day and then remained at or below baseline levels. A majority of Qutenza-treated patients in clinical studies had adverse reactions with a maximum intensity of "mild" or "moderate."

TABLE 1: Treatment-emergent adverse reaction incidence (%) in controlled trials in postherpetic neuralgia (events in $\geq 1\%$ of Qutenza-treated patients and at least 1% greater in the Qutenza group than in the control group)		
Body System Preferred Term	Qutenza 60 minutes (N = 622) %	Control 60 minutes (N = 495) %
GENERAL DISORDERS AND ADMINISTRATION-SITE CONDITIONS		
Application-Site Erythema	63	54
Application-Site Pain	42	21
Application-Site Pruritus	6	4
Application-Site Papules	6	3
Application-Site Edema	4	1
Application-Site Swelling	2	1
Application-Site Dryness	2	1
Infections and Infestations		
Nasopharyngitis	4	2
Bronchitis	2	1
Sinusitis	3	1
Gastrointestinal Disorders		
Nausea	5	2
Vomiting	3	1
Skin and Subcutaneous Tissue Disorder		
Pruritus	2	<1
Vascular Disorders		
Hypertension	2	1

Other Adverse Reactions Observed During the Clinical Studies of Qutenza: General Disorders and Administration-Site Conditions: application-site urticaria, application-site paresthesia, application-site dermatitis, application-site hyperesthesia, application-site excoriation, application-site warmth, application-site anesthesia, application-site bruising, application-site inflammation, application-site exfoliation, peripheral edema

Nervous System Disorders: headache, burning sensation, peripheral sensory neuropathy, dizziness, dysgeusia, hyperesthesia, hypoesthesia

Respiratory, Thoracic, and Mediastinal Disorders: cough, throat irritation

Skin and Subcutaneous Tissue Disorders: abnormal skin odor

DRUG INTERACTIONS

No clinical drug interaction studies have been performed.

Data from *in vitro* cytochrome P450 inhibition and induction studies show that capsaicin does not inhibit or induce liver cytochrome P450 enzymes at concentrations which far exceed those measured in blood samples. Therefore, interactions with systemic medicinal products are unlikely.

USE IN SPECIFIC POPULATIONS

Pregnancy - Category B

There are no adequate and well-controlled studies evaluating Qutenza in pregnant women.

There was no evidence of fetal teratogenicity in embryofetal developmental toxicological studies conducted in pregnant rats and rabbits in which Qutenza patches (rats) or liquid (rabbits) were applied once daily for a 3-hour duration during the period of fetal organogenesis up to doses corresponding to an 11-fold margin over the maximum recommended human dose [MRHD] based on a C_{50} exposure comparison. A peri- and post-natal reproduction toxicology study in rats showed no effects on survival, growth, learning and memory tests, sexual maturation, mating, pregnancy, and fetal development in the offspring of mothers treated with capsaicin up to an 11-fold margin over the MRHD.

Labor and Delivery: The effects of Qutenza on labor and delivery are unknown.

Nursing Mothers: There are no adequate and well-controlled studies in nursing women. Studies in rats have demonstrated capsaicin is excreted into breast milk of this species. It is unknown whether capsaicin is excreted in human breast milk. Because Qutenza is administered as a single 60-minute application and capsaicin is rapidly cleared from the bloodstream, mothers can reduce infant exposure by not breast-feeding after treatment on the day of treatment.

Pediatric Use: The safety and effectiveness of Qutenza in patients younger than 18 years of age have not been studied.

Geriatric Use: In controlled clinical studies of Qutenza in neuropathic pain associated with postherpetic neuralgia, 75% of patients were 65 years and older and 43% of patients were 75 years and older. Safety and effectiveness were similar in geriatric patients and younger patients. No dose adjustments are required in geriatric patients.

OVERDOSAGE

There is no clinical experience with Qutenza overdose in humans.

There is no specific antidote for overdose with capsaicin. In case of suspected overdose, remove patches gently, apply Cleansing Gel for one minute, wipe off with dry gauze and gently wash the area with soap and water. Use supportive measures and treat symptoms as clinically warranted.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility: Adequate carcinogenicity studies have not been conducted with Qutenza or capsaicin. Capsaicin was not mutagenic in the Ames, mouse micronucleus and chromosomal aberration in human peripheral blood lymphocytes assays. As with other catechol-containing compounds (eg, dopamine), capsaicin showed a weak mutagenic response in the mouse lymphoma assay. A fertility and reproductive toxicology study was conducted in rats with exposure to Qutenza patches daily for 3 hours/day beginning 28 days before cohabitation, through cohabitation and continuing through the day before sacrifice (approximately 49 days of treatment). The results revealed a statistically significant reduction in the number and percent of motile sperm. Sperm motility obtained from the vas deferens was reduced in all capsaicin treatment groups (16, 24, and 32 mg capsaicin patch/rat/day). Though a "no effect" level was not determined, dose levels used in the study correspond to a 13- to 28-fold exposure margin over the mean C_{50} associated with the maximal human recommended dose. Sperm counts were reduced in the vas deferens or cauda epididymis in the 24 and 32 mg capsaicin patch/rat/day dose groups (79 and 69%, respectively) compared to the placebo-patch-treated control group; however, these reductions did not adversely affect fertility. As this animal model has a large excess of sperm-generating capacity relative to the threshold necessary for fertilization, the lack of an effect on fertility in this species is of unknown significance for human risk assessment.

DOSE AND ADMINISTRATION

Special precautions: • Only physicians or health care professionals under the close supervision of a physician are to administer Qutenza. • Use only nitrile gloves when handling Qutenza, and when cleaning capsaicin residue from the skin. • Immediately after use, dispose of used and unused patches, cleansing gel, and other treatment materials in accordance with the local biomedical waste procedures. • Use Qutenza only on dry, intact (unbroken) skin.

Dosing: The recommended dose of Qutenza is a single, 60-minute application of up to four patches. Treatment with Qutenza may be repeated every three months or as warranted by the return of pain (not more frequently than every three months).

HANDLING AND DISPOSAL

Qutenza contains capsaicin capable of producing severe irritation of eyes, skin, respiratory tract, and mucous membranes. Do not dispense Qutenza to patients for self-administration. It is critical that health care professionals who administer Qutenza have completely familiarized themselves with proper dosing, handling, and disposal procedures before handling Qutenza to avoid accidental or inadvertent capsaicin exposure to themselves or others [see Dosage and Administration].

Do not touch Qutenza, treatment areas, and all used supplies or other materials placed in contact with the treatment area without wearing nitrile gloves. Wear nitrile gloves at all times while handling Qutenza and cleaning treatment areas. Do NOT use latex gloves. Do not hold Qutenza near eyes or mucous membranes. Immediately after use, dispose of used and unused patches, patch clippings, unused Cleansing Gel, and associated treatment supplies in accordance with local biomedical waste procedures.

PATIENT COUNSELING INFORMATION

See Patient Counseling Information section of the full package insert.

Manufactured for NeurogesX, Inc., San Mateo, CA 94404, USA by Lohmann Therapie-Systeme AG (LTS), Andernach, Germany

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