Project Offers Psychotherapy to Military Families

BY PATRICE WENDLING

Soldiers and their families are being offered free access to psychotherapy across the country.

The Soldiers Project is providing confidential psychotherapy to address the growing need for comprehensive mental health care for military personnel and their families and to stop the transmission of trauma to future generations, according to project founder and director Dr. Judith Broder.

"We know that when people are traumatized and it's not treated that the trauma gets carried on to their children and their children's children, but if there's early intervention and treatment then the traumatized person is less likely to be a transmitter," said Dr. Broder, a psychiatrist and psychoanalyst. "That's the basic impetus—to get in there early and as intensive as possible, and that's a fundamental difference from the services the VA [Veterans Administration] can provide.

"We see soldiers and their families for as long as they need—sometimes for up to 2½ years—for free."

Started in 2004 under the aegis of the Los Angeles Institute and Society of Psychoanalytic Studies, The Soldiers Project now has chapters in the cities of Chicago, Seattle, and Sacramento, and in New York, New Jersey, and southern California. At least 350 soldiers or veterans have been treated. Patients access services via the project's Web site (www.thesoldiersproject.org) or national phone line (877-576-5343) and are matched with a local therapist who has undergone specific training in posttraumatic stress disorder and the military culture.

The project stresses the need for psychological support and education for military families and children, because it can provide a framework for families to understand and talk about deployment, reunions, and transitions during multiple deployments, Dr. Broder said. Soldiers returning home may be changed by combat-related medical conditions or become impatient or withdrawn, while family dynamics can change as children and spouses adapt to fill the void of the missing parent. The uncertainty of whether a soldier will be redeployed is unique to this war and particularly stressful for children and spouses, with many soldiers shutting down as a way to cope with the uncertainty.

'We see soldiers and their families for as long as they need—sometimes for up to 2½ years—for free.'

DR. BRODER

If the slow, painstaking work of psychoanalysis, which Sigmund Freud once likened to archaeological excavation, sounds like an odd match for tight-lipped, action-oriented soldiers, Dr. Broder said the approach is actually well suited. She suggests that in some fundamental way the basic character of many of the young men and women who have served has been shattered, and that this type of wound may be difficult to reach by the more widely used cognitive-behavioral therapy (CBT) with its systematic, goal-oriented approach to influencing dysfunctional behaviors and emotions.

In some cases, the volunteer physicians opt to prescribe medication to the returning soldiers. They do this in addition to providing psychotherapy, she said.

The specific credentials of the therapists tend to be less of an issue than the "proximity of the volunteer's office to the referral request and the time availability," she said.

"We pride ourselves on finding therapists who are close to the people making the request," she said. "Many of the traumatized veterans cannot drive freeways or be in a car or bus for extended periods, as serving in Iraq often exposed them to hidden explosives or rocket-propelled grenades."

In addition, the volunteer therapists try to help the soldiers obtain medications through the VA, since the soldiers must pay for the medication out of pocket if they get them privately. ■

AMRIX® Rx Only

(Cyclobenzaprine Hydrochloride Extended-Release Capsules)

Brief Summary of Prescribing Information. The following is a brief summary only. Please see full Prescribing Information for complete product information.

DESCRIPTION

AMRIX® (Cyclobenzaprine Hydrochloride Extended-Release Capsules) is a skeletal muscle relaxant which relieves muscle spasm of local origin without interfering with muscle function. The active ingredient in AMRIX extended-release capsules is cyclobenzaprine hydrochloride, USP.
AMRIX extended-release capsules for oral administration are supplied in 15 and 30 mg strengths.

INDICATIONS AND USAGE

AMRIX is indicated as an adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful musculoskeletal conditions. Improvement is manifested by relief of muscle spasm and its associated signs and symptoms, namely, pain, tenderness, and limitation of motion.
AMRIX should be used only for short periods (up to two or three weeks) because adequate evidence of effectiveness for more prolonged use is not available and because muscle spasm associated with acute, painful musculoskeletal conditions is generally of short duration and specific therapy for longer periods is seldom warranted.
AMRIX has not been found effective in the treatment of spasticity associated with cerebral or spinal cord disease or in children with cerebral palsy.

CONTRAINDICATIONS

- Hypersensitivity to any component of this product.
- Concomitant use of monoamine oxidase (MAO) inhibitors or within 14 days after their discontinuation.
- Hyperpyretic crisis seizures and deaths have occurred in patients receiving cyclobenzaprine (or structurally similar tricyclic antidepressants) concomitantly with MAO inhibitor drugs.
- During the acute recovery phase of myocardial infarction, and in patients with arrhythmias, heart block conduction disturbances, or congestive heart failure.
- Hyperthyroidism.

WARNINGS

AMRIX is closely related to the tricyclic antidepressants, e.g., amitriptyline and imipramine. In short term studies for indications other than muscle spasm associated with acute musculoskeletal conditions, and usually at doses somewhat greater than those recommended for skeletal muscle spasm, some of the more serious central nervous system reactions noted with the tricyclic antidepressants have occurred (see **WARNINGS**, below, and **ADVERSE REACTIONS** section of full Prescribing Information).
Tricyclic antidepressants have been reported to produce arrhythmias, sinus tachycardia, prolongation of the conduction time leading to myocardial infarction and stroke. AMRIX may enhance the effects of alcohol, barbiturates, and other CNS depressants.
As a result of a two-fold higher cyclobenzaprine plasma levels in subjects with mild hepatic impairment, as compared to healthy subjects, following administration of immediate-release cyclobenzaprine and because there is limited dosing flexibility with AMRIX, use of AMRIX is not recommended in subjects with mild, moderate or severe hepatic impairment.
As a result of a 40% increase in cyclobenzaprine plasma levels and a 56% increase in plasma half-life following administration of AMRIX in elderly subjects as compared to young adults, use of AMRIX is not recommended in elderly.

PRECAUTIONS

General

Because of its atropine-like action, AMRIX should be used with caution in patients with a history of urinary retention, angle-closure glaucoma, increased intraocular pressure, and in patients taking anticholinergic medication.

Information for Patients

AMRIX, especially when used with alcohol or other CNS depressants, may impair mental and/or physical abilities required for performance of hazardous tasks, such as operating machinery or driving a motor vehicle.

Drug Interactions

AMRIX may have life-threatening interactions with MAO inhibitors. (See **CONTRAINDICATIONS**.)
AMRIX may enhance the effects of alcohol, barbiturates, and other CNS depressants. Tricyclic antidepressants may block the antihypertensive action of guanethidine and similarly acting compounds. Tricyclic antidepressants may enhance the seizure risk in patients taking tramadol (ULTRAM® [tramadol HCl tablets, Ortho-McNeil Pharmaceutical] or ULTRACET® [tramadol HCl and acetaminophen tablets, Ortho-McNeil Pharmaceutical]).

Carcinogenesis, Mutagenesis, Impairment of Fertility

In rats treated with cyclobenzaprine for up to 67 weeks at doses of approximately 5 to 40 times the maximum recommended human dose, pale, sometimes enlarged, livers were noted and there was a dose-related hepatocyte vacuolation with lipidosis. Cyclobenzaprine did not affect the onset, incidence, or distribution of neoplasia in an 81-week study in the mouse or in a 105-week study in the rat. At oral doses of up to 10 times the human dose, cyclobenzaprine did not adversely affect the reproductive performance or fertility of male or female rats.
A battery of mutagenicity tests using bacterial and mammalian systems for point mutations and cytogenic effects have provided no evidence for a mutagenic potential for cyclobenzaprine.

Pregnancy

Pregnancy Category B: Reproduction studies have been performed in rats, mice, and rabbits at doses up to 20 times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to cyclobenzaprine. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because cyclobenzaprine is closely related to the tricyclic antidepressants, some of which are known to be excreted in human milk, caution should be exercised when AMRIX is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of AMRIX has not been studied in pediatric patients.

Use in the Elderly

The plasma concentration and half-life of cyclobenzaprine are substantially increased in the elderly when compared to the general patient population (see **CLINICAL PHARMACOLOGY**, ***Pharmacokinetics***, **Special Populations**, *Elderly* in full Prescribing Information). Accordingly, AMRIX should not be used in the elderly.

ADVERSE REACTIONS

The most common adverse reactions in the two 14-day clinical efficacy trials are presented in Table 1.

Table 1: Incidence of the Most Common Adverse Reactions Occurring in ≥3% of Subjects in Any Treatment Group in the Two Phase 3, Double-Blind AMRIX Trials

	AMRIX 15 mg N = 127	AMRIX 30 mg N = 126	Placebo N = 128
Dry mouth	6%	14%	2%
Dizziness	3%	6%	2%
Fatigue	3%	3%	2%
Constipation	1%	3%	0%
Somnolence	1%	2%	0%
Nausea	3%	3%	1%
Dyspepsia	0%	4%	1%

In a postmarketing surveillance program (7607 patients treated with cyclobenzaprine 10 mg TID), the adverse reactions reported most frequently were drowsiness, dry mouth, and dizziness. Among the less frequent adverse reactions, there was no appreciable difference in incidence in controlled clinical studies or in the surveillance program. Adverse reactions which were reported in 1% to 3% of the patients were: fatigue/tiredness, asthenia, nausea, constipation, dyspepsia, unpleasant taste, blurred vision, headache, nervousness, and confusion. The following adverse reactions have been reported in post-marketing experience or with an incidence of less than 1% of patients in clinical trials with the 10 mg TID tablet:
Body as a Whole: Syncope; malaise.
Cardiovascular: Tachycardia; arrhythmia; vasodilatation; palpitation; hypotension.
Digestive: Vomiting; anorexia; diarrhea; gastrointestinal pain; gastritis; thirst; flatulence; edema of the tongue; abnormal liver function and rare reports of hepatitis, jaundice, and cholestasis.
Hypersensitivity: Anaphylaxis; angioedema; pruritus; facial edema; urticaria; rash.
Musculoskeletal: Local weakness.
Nervous System and Psychiatric: Seizures, ataxia; vertigo; dysarthria; tremors; hypertonia; convulsions; muscle twitching; disorientation; insomnia; depressed mood; abnormal sensations; anxiety; agitation; psychosis, abnormal thinking and dreaming; hallucinations; excitement; paresthesia; diplopia.
Skin: Sweating.
Special Senses: Ageusia; tinnitus.
Urogenital: Urinary frequency and/or retention.

DRUG ABUSE AND DEPENDENCE

Pharmacologic similarities among the tricyclic drugs require that certain withdrawal symptoms be considered when AMRIX (Cyclobenzaprine Hydrochloride Extended-Release Capsules) is administered, even though they have not been reported to occur with this drug. Abrupt cessation of treatment after prolonged administration rarely may produce nausea, headache, and malaise. These are not indicative of addiction.

OVERDOSAGE

Although rare, deaths may occur from overdosage with AMRIX. Multiple drug ingestion (including alcohol) is common in deliberate cyclobenzaprine overdose. **As management of overdose is complex and changing, it is recommended that the physician contact a poison control center for current information on treatment.** Signs and symptoms of toxicity may develop rapidly after cyclobenzaprine overdose; therefore, hospital monitoring is required as soon as possible.
All patients suspected of an overdose with AMRIX should receive gastrointestinal decontamination. This should include large volume gastric lavage followed by activated charcoal. If consciousness is impaired, the airway should be secured prior to lavage and emesis is contraindicated.
The principles of management of child and adult overdosage are similar. It is strongly recommended that the physician contact the local poison control center for specific pediatric treatment.

DOSAGE AND ADMINISTRATION

The recommended adult dose for most patients is one (1) AMRIX 15 mg capsule taken once daily. Some patients may require up to 30 mg/day, given as one (1) AMRIX 30 mg capsule taken once daily or as two (2) AMRIX 15 mg capsules taken once daily.
It is recommended that doses be taken at approximately the same time each day.
Use of AMRIX for periods longer than two or three weeks is not recommended (see **INDICATIONS AND USAGE**).
Dosage Considerations for Special Patient Populations: AMRIX should not be used in the elderly or in patients with impaired hepatic function (see **WARNINGS**).

HOW SUPPLIED

AMRIX extended-release capsules are available in 15 and 30 mg strengths, packaged in bottles of 60 capsules.

KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN. IN CASE OF ACCIDENTAL OVERDOSE, SEEK PROFESSIONAL ASSISTANCE OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

Distributed by
Cephalon, Inc., Frazer, PA 19355
Manufactured by Eurand, Inc., Vandalia, Ohio 45377

AMRIX is a trademark of Cephalon, Inc., or its affiliates.
©2004-2009 Cephalon, Inc., or its affiliates. All rights reserved.

AMR-2009P-PM-00289 Rev. 4/2009

Cephalon deliver more