Agency Issues Guidance on 2002 'Born-Alive' Law

BY MARY ELLEN SCHNEIDER

Senior Writer

fficials at the Department of Health and Human Services are trying to encourage enforcement of a 2002 law that defines any live birth as a person.

The agency issued guidance in April that withholding medical care from an infant born alive may constitute a violation of the federal Emergency Medical Treatment and Labor Act (EMTALA) and the Medicare Conditions of Participation.

Officials also notified state agencies that receive grants under the Child Abuse Prevention and Treatment Act that they must have procedures in place to respond to any reports of medical neglect of "born-alive infants.'

The Born-Alive Infants Protection Act, which was enacted in August 2002, establishes a definition of the terms "individual," "person," "human being," or "child"

as any infant who is born alive, at any stage of development.

The federal law (P.L. 107-207) states that born alive," with respect to a member of the species *Homo sapiens*, means the "complete expulsion or extraction from his or her mother of that member, at any stage of development, who after such expulsion or extraction breathes or has a beating heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, regardless of whether the umbilical cord has been cut, and regardless of whether the expulsion or extraction occurs as a result of natural or induced labor, cesarean section, or induced abortion."

But the law doesn't mean much medically, according to David Grimes, M.D., an ob.gyn. in Chapel Hill, N.C., and the former chief of the abortion surveillance branch at the Centers for Disease Control and Prevention."The medical impact is negligible," Dr. Grimes said.

If the law is followed to the letter, he said, it will classify more miscarriages as live births and ultimately infant deaths, giving the United States a statistically worse infant mortality.

The American College of Obstetricians and Gynecologists issued an opinion at the time the law was enacted, saying that the statute did not require physicians to make changes to the standard of care.

The act does not dictate the standard of care to be given to premature infants. It merely provides a definition and does not impose any requirements, restrictions, or penalties," Ralph W. Hale, M.D., ACOG's executive vice president, said in a message to the membership in 2002. "Fellows should be familiar with their states' laws and should consult their local attorneys if they have any questions," he said.

HHS decided to issued the guidance nearly 3 years after the enactment of the law—because the department recently received several questions about whether it was planning to issue regulations to implement the law, HHS Secretary Mike Leavitt said in a statement. However, the department would not release information on whether any violations had occurred.

In its guidance, HHS said there are some circumstances where EMTALA protections can be applied to an infant who is born alive under the law.

For example, if an infant were born alive, under the definition in the law, at the hospital, and a prudent layperson could conclude that the infant was suffering from an emergency medical condition based on appearance or behavior, the hospital and medical staff would be required to perform a medical screening.

If an emergency condition existed, the staff would be obligated under EMTALA to either admit the infant or stabilize and transfer him or her. Under EMTALA, each violation can cost a physician up to

David W. Hager, M.D., an ob.gyn. in Lexington, Ky., and a member of the Christian Medical Association, agrees that the majority of physicians have been adhering to the law. However, he said, it's important to ensure that it is being implemented across the board, even in cases where the live birth is the result of an abortion. And all physicians need to be aware of their responsibilities under the law to screen infants who are born alive, and to stabilize and transfer them when appropriate, he said.

But Vicki Saporta, president and CEO of the National Abortion Federation, said the 2002 law seems unnecessary since physicians were and are abiding by state and federal laws that protect the legal rights of infants from birth.



INDICATIONS AND USAGE
LUNESTA is indicated for the treatment of insomnia. In controlled outpatient and sleep
laboratory studies, LUNESTA administered at bedtime decreased sleep latency and

WARNINGS

Because sleep disturbances may be the presenting manifestation of a physical and/or psychiatric disorder, symptomatic treatment of insomnia should be initiated only after a careful evaluation of the patient. The failure of insomnia to remit after 7 to 10 days of treatment may indicate the presence of a primary psychiatric and/or medical lineas that should be evaluated. Worsening of insomnia or the emergence of new thinking or behavior abnormalities may be the consequence of an unrecognized psychiatric or physical disorder. Such findings have emerged during the course of treatment with sedative/hypontic drugs, including LUNESTA. Because some of the important adverse effects of LUNESTA appear to be dose-related, it is important to use the lowest possible effective dose, sepecially in the elderly (see DOSAGE AND ADMINIS-TRATION in the Full Prescribing Information).

convest possible effective dose, aspecially in the elderly (see DOSAGE AND ADMINISTRATION in the Full Prescribing Information).

A variety of abnormal thinking and behavior changes have been reported to occur in association with the use of sedative/hypnotics. Some of these changes may be characterized by decreased inhibition (e.g., aggressiveness and extroversion that seem out of character), similar to effects produced by alcohol and other CNS depressants. Other reported behavioral changes have included bizarre behavior, agitation, hallucinations, and depersonalization. Amnesia and other neuropsychiatric symptoms may occur unpredictably. In primarily depressed patients, worsening of depression, including suicidal trinking, has been reported in association with the use of sedative/hypnotics.

It can rarely be determined with certainty whether a particular instance of the abnormal behaviors isisted above are drug-induced, spontaneous in origin, or a result of an underlying psychiatric or physical disorder. Monetheless, the emergence of any new behavioral sign or symptom of concern requires careful and immediate evaluation. Following rapid dose decrease or abrugt discontinuation of the use of seature/hypnotics, there have been reports of signs and symptoms similar to those associated with withdrawal from other CNS-depressant offects. Because of the rapid donest of action, LUNESTA bould only be ingested immediately prior to going to bed or after the patient has gone to bed and has experienced difficulty falling asleep. Patients receiving LUNESTA should only be ingested immediately prior to going to bed or after the patient has gone to bed and has experienced difficulty falling asleep. Patients receiving LUNESTA should only be ingested immediately prior to going to bed or after the patient has gone to bed and has experienced difficulty falling asleep. Patients receiving LUNESTA should only be ingested immediately prior to going to be a crafter the patients of the patients receiving LUNESTA should only be ingested im

Timing 01 Drug Administration: LUNESTA should be taken immediately before bedtime Taking a sedative/hypnotic while still up and about may result in short-term memory impairment, hallucinations, impaired coordination, dizziness, and lightheadedness.

Use in The Elderly And/Or Debilitated Patients: Impaired motor and/or cognitive performance after repeated exposure or unusual sensitivity to sedative/hyponicidings is a concern in the treatment of elderly and/or debilitated patients. The recommended starting dose of LUNESTA for these patients is 1 mg (see DOSAGE AND ADMINISTRATION in the Full Prescribing Information).

Use In Patients With Concomitant Illness: Clinical experience with eszopiclone in patients with concomitant illness is limited. Eszopiclone should be used with caution in patients with diseases or conditions that could affect metabolism or hemodynamic

responses.

A study in healthy volunteers did not reveal respiratory-depressant effects at doses 2.5-fold higher (7 mg) than the recommended dose of eszopicione. Caution is advised, however, if LIMESTA is prescribed to patients with compromised respiratory function. The dose of LIMESTA should be reduced to 1 mg in patients with severe hepatic impairment, because systemic exposure is doubled in such subjects. No dose adjustment appears necessary for subjects with mild or moderate hepatic impairment, dose adjustment appears necessary in subjects with any degree of renal impairment, since less than 10% of eszopicione is excreted unchanged in the urine.

since less than 10% of eszopiclone is excreted unchanged in the urine.
The dose of LUNESTA should be reduced in patients who are administered potent
inhibitors of CYP3A4, such as ketoconazole, while taking LUNESTA. Downward dose
adjustment is also recommended when LUNESTA is administered with agents having known CNS-depressant effects.

Use In Patients With Depression: Seditive/hypnotic drugs should be administered
with caution to patients exhibiting signs and symptoms of depression. Suicidal tendencies may be present in such patients, and protective measures may be required.
Intertional overdose is more common in this group of patients: therefore, the less
amount of drug that is feasible should be prescribed for the patient at any one time.
Information For Patients: Patient Information is printed in the complete prescribing
information.

Laboratory Tests: There are no specific laboratory tests recommended.

Channot An additive effect on psychomotor performance was seen with coadministra-tion of eszopiclone and ethanol 0.70 g/kg for up to 4 hours after ethanol administration. Parroxetine: Coadministration of single doses of eszopiclone 3 mg and paroxetine 20 mg daily for 7 days produced no pharmacokinetic or pharmacodynamic interaction.

2 mg did not have clinically relevant effects on the pharmacodynamics or pharmacokinetics of etither drug.

**Olanzapine: Coadministration of eszopiclone 3 mg and olanzapine 10 mg produced a
decrease in DSST scores. The interaction was pharmacodynamic; there was no alteration in the pharmacokinetics of either drug.

**Drugs That Inhibit CYP3A4 (Retoconazole): CYP3A4 is a major metabolic pathway for
elimination of eszopiclone. The ALUC of eszopiclone was increased 2.2-fold by coadministration of ketoconazole, a potent inhibitor of CYP3A4, 400, mg daily for 5 days.

**Crean drug vere increases 1.4-fold and 1.3-fold, respectively. One fisting inhibitors

of CYP3A4 (e.g., traconazole, clarithromycin, nefazodone, trolleandomycin, ritonavir,
nefineavir) would be expected to be behave similar ferency.

**Program of the control of the c

Drugs With A Narrow Therapeutic Index
Digoxin: A single dose of eszopicione 3 mg did not affect the pharmacokinetics of
digoxin measured at steady state following dosing of 0.5 mg twice daily for one day
and 0.25 mg daily for the next 6 days.

Warfarin: Eszopicione 8 mg administered daily for 5 days did not affect the pharmacokinetics of (R)- or (S)-warfarin, nor were there any changes in the pharmacodynamic profile (prothrombin time) following a single 25-mg oral dose of warfarin.

Carcinogenesis, Mutagenesis, Impairment of Fertility
Carcinogenesis: In a carcinogenicity study in Sprague-Dawley rats in which eszopiclone was given by oral gavage, no increases in tumors were seen; plasma levels
(AUC) of eszopicione at the highest dose used in this study (16 mg/kg/day) are estimated to be 80 (lemates) and 20 (males) times those in humans receiving the maximum recommended human dose (MRHD). However, in a carcinogenicity study in

Sprague-Dawley rats in which racemic zopicione was given in the diet, and in which plasma levels of eszopicione were reached that were greater than those reached in the above study of eszopicione, an increase in mammary gland adenocarionmas in females and an increase in thyroid gland follicular cell adenomas and carcinomas in females were seen at the highest dose of 100 mg/kg/day. Plasma levels of eszopicione at this dose are estimated to be 150 (females) and 70 (males) times those in humans receiving the MRHD. The mechanism for the increase in strong significant concernation of the secondary to increase in thyroid tumors is thought to be due to increased levels of TSH secondary to increase in thyroid tumors is thought to be due to increased levels of TSH secondary to increase in thyroid tumors is thought to be due to increased levels of TSH secondary to increase in the relation of the manual properties. In a carcinogenicity study in B603F1 mice in which racemic zopicione was given in the diet, an increase in pulmonary carcinomas and carcinomas plus adenomas in females and an increase in skin fibromas and sarcomas in males were seen at the highest dose of 100 mg/kg/day, Plasma levels of eszopicione at this dose are estimated to be 8 (females) and 20 (males) times those in humans receiving the MRHD. The shirt tumors were due to skin lesions induced by aggressive behavior, a mechanism that is not relevant to humans. A carcinogenicity study was also performed in which CD-1 mice were given eszopicione at doses up to 100 mg/kg/day by oral gazage; although this study did not reach a maximum tolerated dose, and was thus inadequate for overal assessment of carcinogenicity study was also performed in which received the total carcinogenicity study was also performed in which the study did not reach a maximum tolerated dose, and was thus inadequate for overal assessment of carcinogenic potential, no increases in mitter received the study.

copicione did not increase tumors in a p53 transgenic mouse bioassay at oral ses up to 300 mg/kg/day.

doses up to 300 mg/kg/day.

Mutagenesis: Escopicione was positive in the mouse lymphoma chromosomal aberration assay and produced an equivocal response in the Chinese hamster ovary cell chromosomal aberration assay. It was not mutagenic or clastogenic in the bacterial Ames gene mutation assay, in an unscheduled DNA synthesis assay, or in an invivo mouse bone marrow micronucleus assay.

(S)-N-desmethyl zopicione, a metabolite of escopicione, was positive in the Chinese hamster ovary cell and human lymphocyte chromosomal aberration assays. It was negative in the bacterial Ames mutation assay, in an in vitro xP-postlabeling DNA adduct assay, and in an in vivo mouse bone marrow chromosomal aberration and micronucleus assay.

micronucleus assay.

Impairment Of Fertifity: Eszopicione was given by oral gavage to male rats at doses up to 45 mgk/gday from 4 weeks premating through mating and to female rats at doses up to 180 mg/kg/day from 2 weeks premating through day 7 of pregnancy. An additional study was performed in which only females were treated, up to 180 mg/kg/day. Eszopicione decreased fertility, probably because of effects in both males and females, with no females becoming pregnant when both males and females were treated with the highest dose; the no-effect dose in both sexes was 5 mg/kg (16 timas the MRHD on a mg/m² basis). Other effects included increased preimplantation loss (no-effect dose 25 mg/kg), and decreases in sperm number and molitily and increases in morphologically abnormal sperm (no-effect dose 5 mg/kg).

phologically ahnormal sperm (no-effect dose 5 mg/kg).

Pregnancy

Nursing Mothers: It is not known whether LUNESTA is excreted in human milk Because many drugs are excreted in human milk, caution should be exercised when LUNESTA is administered to a nursing woman.

Pediatric Use: Safety and effectiveness of eszopiclone in children below the age of 18 have not been established.

have not been established.

Geriatric Use: A total of 287 subjects in double-blind, parallel-group, placebo-controlled clinical trials who received eszopictione were 65 to 86 years of age. The overall pattern of adverse events for elderly subjects (median age = 71 years) in 2-week studies with night time dosing of 2 mg eszopictione was not different from that seen in younger adults. LUNESTA 2 mg exhibited significant reduction in sleep latency and improvement in sleep maintenance in the elderly population.

Improvement in sleep maintenance in the etoemy population.

ADVERSE REACTIONS
The premarketting development program for LUNESTA included eszopicione exposures in patients and/or normal subjects from two different groups of studies; approximately 400 normal subjects in clinical pharmacology/bharmacokinetic studies, and approximately 1550 patients in placebo-controlled clinical effectiveness studies, corresponding to approximately 263 patient-exposure years. The conditions and duration of treatment with LUNESTA varied greatly and included (in overlapping categories) open-label and double-blind phases of studies, inpatients and outpatients, and short-term and longer-term exposure. Adverse reactions were assessed by collecting adverse events, results of physical examinations, vital signs, weights, laboratory analyses, and ECGs.

assessed by collecting adverse events, results of physical examinations, vital signs, weights, laboratory analyses, and ECGs.

Adverse events during exposure were obtained primarily by general inquiry and recorded by clinical investigators using terminology of their own choosing. Consequently, it is not possible to provide a meaningful estimate of the proportion of individuals experiencing adverse events without first grouping similar types of events into a smaller number of standardized event categories. In the tabulations that follow, COSTART terminology has been used to classify reported adverse events.

The stated frequencies of adverse events represent the proportion of individuals who experienced, aleast once, a treatment-emergent adverse event of the type listed. An event was considered treatment-emergent if if occurred for the first time or worsened while the patient was receiving therapy following baseline evaluation.

Adverse Findings Observed in Placebo-Controlled Trials

Adverse Events Resulting in Discontinuation of Treatment. In placebo-controlled, parallel-group clinical trials in the elderly, 3.8% of 208 patients who received placebo. 2.3% of 215 patients who received Tamp LUNESTA discontinued treatment due to an adverse event. In the 6-week parallel-group study in adults, no patients in the 3 mg arm discontinued because of an adverse event in the 6-week parallel-group study in adults, no patients in the 3 mg arm discontinued because of an adverse who received placebo and 12.8% of 593 gatients who received placebo. Controlled Trials. The following the properties of the properties of the placebo and 12.8% of 593 gatients who received placebo and 12.8% of 593 gatients who received placebo and 12.8% of 593 gatients who received placebo and 12.8% of 593 gatients who r

resulted in discontinuation occurred at a rate of greater than 2%.

Adverse Events Observed at an Incidence of 22% in Controlled Trials. The following lists the incidence (%) placebo, 2 mg, 3 mg, respectively) of treatment-emergent adverse events from a Phase 3 placebo-controlled study of LUNESTA at doses of 2 or 3 mg in on-elderly adults. Treatment duration in this trial was 44 days. Data are limited to adverse events that occurred in 2% or more of patients treated with LUNESTA 2 mg (n=104) or 3 mg (n=105) in which the incidence in placebo-treated patients treated with LUNESTA 2 mg (n=104) or 3 mg (n=105) in which the incidence in placebo-treated patients treated with LUNESTA 2 mg (n=104) or 3 mg (n=105) in which the incidence in placebo-treated patients (n=99). Body as a whole; headache (13%, 21%, 17%), origin infection (1%, 3%, 3%, 18%), somptime (1%, 3%, 4%), vomiting (1%, 3%, 6%), 6%, 5%, 7%), syspepsia (4%, 4%, 5%), naisae (4%, 5%, 4%), vomiting (1%, 3%, 6%), depression (0%, 4%, 1%, 3%), liziness (4%, 5%, 10%, 3%, 18%), shannal angendages; rash (1%, 3%, 4%). Smedial senses; unpleasant taste (3%, 17%, 34%), Linnaential sestem. Observed or 16 media.

'Events for which the LUNESTA incidence was equal to or less than placebo are not listed, but included the following: abnormal dreams, accidental injury, back pain, diarrhea, flu syndrome, myalgia, pain, pharyngitis, and rhinitis. Advarse events that suggest a dose-response relationship in adults include viral infection, dry mouth, dizzness, hallucinations, infection, rash, and unpleasant taste, with this relationship clearest for unpleasant taste. With this relationship clearest for unpleasant taste, with this relationship clearest for moembined Phase 3 placebo-controlled studies of LUNESTA at doses of 1 or 2 mg in elderly adults (agus 65-68). Treatment duration in these trials was 14 days. Data are limited to events that occurred in 2% or more of patients treated with LUNESTA in mg (n=72) or 2 mg (n=215) in which the incidence in patients treated with LUNESTA was greater than the incidence in placebo-treated optients.

listed, but included the following: abdominal pain, asthenia, nausea, rash, and somnolence.

Adverse events that suggest a dose-response relationship in elderly adults include pain, dry mouth, and unpleasant taste, with this relationship again clearest for unpleasant taste. These figures cannot be used to predict the incidence of adverse events in the course of usual medical practice because patient characteristics and other factors may differ from those that prevailed in the clinical trials. Similarly, the clied frequencies cannot be compared with figures obtained from other clinical investigations involving different treatments, uses, and investigators.

The cited figures, however, do provide the prescribing physician with some basis for estimating the relative contributions of drug and non-drug factors to the adverse event incidence rate in the population studied.

Other Events Observed During The Premarketting Evaluation Of LUNESTA. Allowing is a list of modified COSTART terms that reflect treatment-emergent adverse events as defined in the introduction to the ADVERSE REACTIONS section and reported by approximately 1550 subjects resteated with LUNESTA at doses in the range of 1 to 3.5 mg/day during Phase 2 and 3 clinical trials throughout the United States and Canada. All reported events are included except times already silection and events unlikely to be drug-related. Although the events reported occurred during treatment with LUNESTA, they were not necessarily caused by it.

Events are listed in order of decreasing frequency according to the following definions: frequent adverse events are those that occurred in fewer than 171.000 patients; rare adverse events are those that occurred in fewer than 171.000 patients, read events are relosed to the adverse events are those that occurred in fewer than 171.000 patients, read events are relosed to events are relosed to according to the following definitions: frequents but in at least 171,000 patients; read evere events are those that occurred in fewer than 171

occurred in fewer than 1/1,000 patients. Gender-specific events are categorized based on their incidence for the appropriate gender.

Frequent: chest pain, migralne, peripheral edema.

Infrequent: acne, agitation, allergic reaction, alopecia, amenorrhea, anemia, anorexia, apathy, athritis, asthma, ataka, breast engorgement, breast enlargement breast neoplasm, breast pain, bronchitis, burstis, cellulifus, cholelithiasis, conjunctivitis, contact dermatilis, cystibis, dry eyes, dry skin, dysprae, dyspria, eczema, ear piain, emotional lability, epistaxis, face edema, famale lactation, fever, halitosis, heat stroke, lematuria, herrita, licicup, hostility, hypercholestermia, hypertension, hypertension, hypertension, hypertension, brayesthesia, incoordination, increased appetite, insornia, joint disorder (mainly swelling, stiffens, and pain), kidney exidusts, kidney pain, Lamyrigits, leg cramps, lymphadenopathy, malaise, mastitis, melena, memory impairment, menorrhagia, mouth ulceration, mysatenian, acker gird, reurosis, nysagmus, oitis section, ditis media, paresthesia, photosensitivity, reflexes decreased, skin discoloration, sweating, thinking abornal (mainly difficulty concentration), thirst, minutus, kitching, ulcerative stomatitis, uniary frequency, urinary incontinence, uricaria, uterine hemorrhage, vaginal hemorrhage, vaginitis, vertigo, vestibular disorder, veigit gain, veight lostis, dehydration, dysphagia, erythema multiforme, euriphoria, furunculosis, gastristis, gout, hepatitis, hepatomegaly, herpes zoster, hirsutism, hyperacusis, hypersethesia, hypertipemia, hypokalemia, hypokinesia, distilis, liver damage, maculopapolar rash, mydraliss, uroquage, team proprietty, oliguria, photophobia, ptosis, pyelonephritis, rectal hemorrhage, stomach ulcer, stomatitis, changes, morphopholishis, tongue edema, tremor, urethritis, vescicubullous rash.

vesiculobullous rash.

DRUG ABUSE AND DEPENDENCE
Controlled Substance Class: LUNESTA is a Schedule IV controlled substance under the Controlled Substances Act. Other substances under the same classification are benzodiazepines and the nonbenzodiazepine hypnotics zaleplon and zolpidem. While escopidone is a hypnotic agent with a chemical structure unrelated to benzodiazepines, it shares some of the pharmacologic properties of the benzodiazepines.

escopicione is a hypnotic agent with a chemical structure unrelated to benzodiazepines, is shares some of the pharmacologic properties of the benzodiazepines. Abuse, Dependence, and Tolerance Abuse, Dependence; no a study of abuse liability conducted in individuals with known histories of henzodiazepine abuse, eszopicione at doses of 6 and 12 mg produced euphonic effects similar to those of diazepam 20 mg. In this study, at doses 2-fold or greater than the maximum recommended doses, a dose-related increase in reports of amnesia and hallucinations was observed for both LUNESTA and diazepam. The clinical trial experience with LUNESTA revealed no evidence of a serious withdrawal syndrome. Nevertheless, the following adverse events included in DSM-Tolerateria for uncomplicated scalario-Phynolic windrawal were reported during clinical trials following placebo substitution occurring within 48 hours following the last LUNESTA treatment: anxiety, abnormal dreams, nausea, and upset stormach. These upported adverse events occurred at an incidence of 2% or less. Use of benzodiazepines and similar agents may lead to physical and psychological dependence. The risk of abuse and dependence increases with the dose and duration of treatment and concomitant use of other psychoactive drugs. The risk is also greater for patients who have a history of alcohol or ding abuse or history of psychiatric disorders. These patients should be under careful surveillance when receiving LUNESTA or any other hypnotic.

Tolerance: Some loss of efficacy to the hypnotic effect of benzodiazepines and benzo-diazepine-like agents may develop after repeated use of these drugs for a few weeks onzepnie-like agents may develop anter repeated use of inese drugs for a few weeks. No development of tolerance to any parameter of sleep measurement was observed over six months. Tolerance to the efficacy of LUNESTA3 mg was assessed by 4-week objective and 6-week subjective measurements of time to sleep oriset and sleep main-tenance for LUNESTA in a placebo-controlled 44-day study, and by subjective assess-ments of time to sleep onset and WASO in a placebo-controlled study for 6 months.

UVENUOSAGE

There is limited premarketing clinical experience with the effects of an overdosage of LUNESTA. In clinical trials with eszopiclone, one case of overdose with up to 36 mg of eszopiclone was reported in which the subject fully recovered. Individuals have fully recovered from reacemic zopiclone overdoses up to 340 mg (56 times the maximum recommended dose of eszopiclone).

maximum recommended dose of eszopicione).

Signs And Symptoms: Signs and symptoms of overdose effects of CNS depressants can be expected to present as exaggerations of the pharmacological effects noted in preclinical testing. Impairment of consciousness ranging from somnolence to come has been described. Rare individual instances of Itaal outcomes following overdose with racemic zopicione have been reported in Europeen postamarketing reports, most often associated with overdose with other CNS-depressant agents.

Recommended Teatment General symptomatic and supportive measures should be administered as needed. Flumazenli may be useful. As in all cases of drug overdose, respiration, pulse, blood pressure, and other appropriate signs should be monitored and general supportive measures employed. Hypotension and CNS depression should be monitored and treated by appropriate medical intervention. The value of dialysis in the treatment of overdosage has not been determined.

Poison Control Center. As with the management of all overdosage, the possibility of multiple drug ingestion should be considered. The physician may wish to consider or output of the product overdosage.

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