

VALIUM[®] diazepam/Roche

Before prescribing, please consult complete product information, a summary of which follows:

Indications: Management of anxiety disorders, or short-term relief of symptoms of anxiety; symptomatic relief of acute agitation, tremor, delirium tremens and hallucinosis due to acute alcohol withdrawal; adjunctively in skeletal muscle spasm due to reflex spasm to local pathology; spasticity caused by upper motor neuron disorders; athetosis; stiff-man syndrome; convulsive disorders (not for sole therapy).

The effectiveness of Valium in long-term use, that is, more than 4 months, has not been assessed by systematic clinical studies. The physician should periodically reassess the usefulness of the drug for the individual patient.

Contraindicated: Known hypersensitivity to the drug. Children under 6 months of age. Acute narrow angle glaucoma; may be used in patients with open angle glaucoma who are receiving appropriate therapy.

Warnings: Not of value in psychotic patients. Caution against hazardous occupations requiring complete mental alertness. When used adjunctively in convulsive disorders, possibility of increase in frequency and/or severity of grand mal seizures may require increased dosage of standard anticonvulsant medication; abrupt withdrawal may be associated with temporary increase in frequency and/or severity of seizures. Advise against simultaneous ingestion of alcohol and other CNS depressants. Withdrawal symptoms similar to those with barbiturates and alcohol have been observed with abrupt discontinuation, usually limited to extended use and excessive doses. Infrequently, milder withdrawal symptoms have been reported following abrupt discontinuation of benzodiazepines after continuous use, generally at higher therapeutic levels, for at least several months. After extended therapy, gradually taper dosage. Keep addiction-prone individuals under careful surveillance because of their predisposition to habituation and dependence.

Usage in Pregnancy: Use of minor tranquilizers during first trimester should almost always be avoided because of increased risk of congenital malformations as suggested in several studies. Consider possibility of pregnancy when instituting therapy; advise patients to discuss therapy if they intend to or do become pregnant.

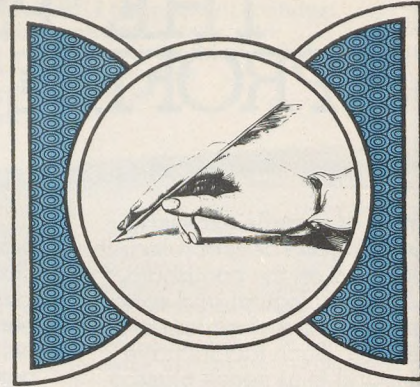
Precautions: If combined with other psychotropics or anticonvulsants, consider carefully pharmacology of agents employed; drugs such as phenothiazines, narcotics, barbiturates, MAO inhibitors and other anti-depressants may potentiate its action. Usual precautions indicated in patients severely depressed, or with latent depression, or with suicidal tendencies. Observe usual precautions in impaired renal or hepatic function. Limit dosage to smallest effective amount in elderly and debilitated to preclude ataxia or oversedation.

Side Effects: Drowsiness, confusion, diplopia, hypotension, changes in libido, nausea, fatigue, depression, dysarthria, jaundice, skin rash, ataxia, constipation, headache, incontinence, changes in salivation, slurred speech, tremor, vertigo, urinary retention, blurred vision. Paradoxical reactions such as acute hyperexcited states, anxiety, hallucinations, increased muscle spasticity, insomnia, rage, sleep disturbances, stimulation have been reported; should these occur, discontinue drug. Isolated reports of neutropenia, jaundice; periodic blood counts and liver function tests advisable during long-term therapy.

Dosage: Individualize for maximum beneficial effect. **Adults:** Anxiety disorders, symptoms of anxiety, 2 to 10 mg b.i.d. to q.i.d.; alcoholism, 10 mg t.i.d. or q.i.d. in first 24 hours, then 5 mg t.i.d. or q.i.d. as needed; adjunctively in skeletal muscle spasm, 2 to 10 mg t.i.d. or q.i.d.; adjunctively in convulsive disorders, 2 to 10 mg b.i.d. to q.i.d. **Geriatric or debilitated patients:** 2 to 2½ mg, 1 or 2 times daily initially, increasing as needed and tolerated. (See Precautions.) **Children:** 1 to 2½ mg t.i.d. or q.i.d. initially, increasing as needed and tolerated (not for use under 6 months).

Supplied: Valium[®] (diazepam/Roche) Tablets, 2 mg, 5 mg and 10 mg—bottles of 100 and 500; Tel-E-Dose[®] packages of 100, available in trays of 4 reverse-numbered boxes of 25, and in boxes containing 10 strips of 10; Prescription Paks of 50, available in trays of 10.

Letters to the Editor



The Journal welcomes Letters to the Editor; if found suitable, they will be published as space allows. Letters should be typed double-spaced, should not exceed 400 words, and are subject to abridgment and other editorial changes in accordance with journal style.

Effectiveness of Patient Education

To the Editor:

I am concerned that Dr. Webb's article on the lack of effectiveness of patient education (*Effectiveness of patient education and psychosocial counseling in promoting compliance and control among hypertensive patients. J Fam Pract 10: 1047, 1980*) may be regarded as a significant argument against the devotion of care delivery resources toward patient education, in the name of cost effectiveness. The discussion and conclusions dealt with some qualifications and limitations of the study, but several key aspects were omitted from consideration.

No data were given regarding the baseline pill count compliance rates and post-intervention rates. The most critical compliance indicator was lumped with pill bringing behavior—a desirable, but certainly secondary behavior. How much room for improved compliance was there, and how much improvement occurred in each group by pill count? Also unmentioned in the methods section is an explanation of how pill count compliance was entered into the combined bringing-

and-consuming rating for visits where the patient did not bring his/her medication.

No mention is made of the number of blood pressure measurements taken on each visit. At least two, and preferably three readings per visit, ideally separated by at least a minute, are necessary to minimize variability of individual blood pressure over time during a visit, and intra- and inter-observer variability in blood pressure measurement performance.¹ Also, one wonders why diastolic blood pressure only was reported on, with ample evidence in the Framingham Study² and others indicating the equal or greater importance of control of systolic blood pressure.

A major educational point is that the once-a-month frequency of intervention, while probably adequate for follow-up reinforcement, is suboptimal for the initial facilitation of significant changes in knowledge, attitudes, or behavior in most target areas. A fertile area for research in family practice is the def-

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ROCHE

Roche Laboratories
Division of Hoffmann-La Roche Inc.
Nutley, New Jersey 07110

INDICATIONS: Based on a review of this drug by the National Academy of Sciences—National Research Council and/or other information, FDA has classified the indications as follows:

"Lacking substantial evidence of effectiveness as a fixed combination." For the symptomatic relief of cough in conditions such as: the common cold, acute bronchitis, allergic asthma, bronchiolitis, croup, emphysema, tracheobronchitis.

Final classification of the less-than-effective indications requires further investigation.

CONTRAINDICATIONS:

Use in Newborn or Premature Infants: This drug should not be used in newborn or premature infants.

Use in Nursing Mothers: Because of the higher risk of antihistamines, codeine and sympathomimetic amines for infants generally and for newborn and premature in particular, Actifed-C Expectorant therapy is contraindicated in nursing mothers.

Use in Lower Respiratory Disease: Antihistamines should not be used to treat lower respiratory tract symptoms including asthma.

Actifed-C Expectorant is also contraindicated in the following conditions:

Hypersensitivity to: 1) Triprolidine Hydrochloride and other antihistamines of similar chemical structure; 2) sympathomimetic amines including pseudoephedrine; and/or 3) any of the other ingredients.

Monoamine oxidase inhibitor therapy (see Drug Interaction Section).

WARNINGS: Actifed-C Expectorant should be used with considerable caution in patients with:

- | | |
|--|------------------------|
| Increased intraocular pressure (Narrow angle glaucoma) | Hypertension |
| Stenosing peptic ulcer | Diabetes mellitus |
| Pyloroduodenal obstruction | Ischemic heart disease |
| Symptomatic prostatic hypertrophy | Hyperthyroidism |
| Bladder neck obstruction | |

Sympathomimetics may produce central nervous stimulation with convulsions or cardiovascular collapse with accompanying hypotension.

Codeine can produce drug dependence of the morphine type, and therefore has the potential of being abused.

Use in Children: As in adults, the combination of an antihistamine and sympathomimetic amine can elicit either mild stimulation or mild sedation in children.

While it is difficult to predict the result of an *overdosage* of a combination of triprolidine, pseudoephedrine, and codeine the following is known about the individual components:

In infants and children especially, antihistamine in overdosage may cause hallucination, convulsion or death. Large doses of pseudoephedrine are known to cause weakness, lightheadedness, nausea and/or vomiting. An overdosage of codeine may cause CNS depression with muscular twitching and convulsion, weakness, disturbed vision, dyspnea, respiratory depression, collapse and coma.

Use in Pregnancy: Experience with this drug in pregnant women is inadequate to determine whether there exists a potential for harm to the developing fetus.

Use with CNS Depressants: Triprolidine and codeine phosphate have additive effects with alcohol and other CNS depressants (hypnotics, sedatives, tranquilizers, etc.).

Use in Activities Requiring Mental Alertness: Patients should be warned about engaging in activities requiring mental alertness as driving a car or operating appliances, machinery, etc.

Use in the Elderly (approximately 60 years or older): Antihistamines are more likely to cause dizziness, sedation and hypotension in elderly patients. Overdosages of sympathomimetics in this age group may cause hallucinations, convulsions, CNS depression, and death.

PRECAUTIONS: Actifed-C Expectorant should be used with caution in patients with: history of bronchial asthma, increased intraocular pressure, hyperthyroidism, cardiovascular disease, hypertension.

DRUG INTERACTIONS: MAO inhibitors prolong and intensify the anticholinergic (drying) effects of antihistamines and overall effects of sympathomimetics. Sympathomimetics may reduce the antihypertensive effects of methyldopa, decamylamine, reserpine, and veratrum alkaloids.

The CNS depressant effect of triprolidine hydrochloride and codeine phosphate may be additive with that of other CNS depressants.

ADVERSE REACTIONS:

- General:** Urticaria, drug rash, anaphylactic shock, photosensitivity, excessive perspiration, chills, dryness of mouth, nose and throat.
- Cardiovascular System:** Hypotension, headache, palpitations, tachycardia, extrasystoles.
- Haematologic System:** Hemolytic anemia, thrombocytopenia, agranulocytosis.
- Nervous System:** Sedation, sleepiness, dizziness, disturbed coordination, fatigue, confusion, restlessness, excitation, nervousness, tremor, irritability, insomnia, euphoria, paresthesias, blurred vision, diplopia, vertigo, tinnitus, acute labyrinthitis, hysteria, neuritis, convulsions, CNS depression, hallucination.
- G.I. System:** Epigastric distress, anorexia, nausea, vomiting, diarrhea, constipation.
- G.U. System:** Urinary frequency, difficult urination, urinary retention, early menses.
- Respiratory System:** Thickening of bronchial secretions, tightness of chest and wheezing, nasal stuffiness.

NOTE: Guaifenesin has been shown to produce a color interference with certain clinical laboratory determinations of 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA).

HOW SUPPLIED: Bottles of 1 pint, 1 gallon and 4 oz Unit of Use Bottle with Child Resistant Cap.

LETTERS TO THE EDITOR

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initiation of optimal intervals for initial and follow-up education efforts, especially in the area of chronic diseases and disease risk factors.

Most importantly, it seems that the opportunity for demonstrating significant lowering of blood pressure by any intervention was very seriously undermined by more than one half (52 percent) of the subjects in the "uncontrolled hypertension" study having pretreatment baseline diastolic blood pressures of 90 mmHg or lower. The effective "n" actually is closer to 59, rather than 123—probably too small to demonstrate significant effects when distributed among three intervention groups.

I applaud Dr. Webb's efforts to examine critically some important questions in the swampy patient education process. It is almost impossible to do faultless research in this area, but good progress is being made toward more effective strategies and techniques.

Regarding Dr. Geyman's editorial about patient education,³ I would like to add two practical recommendations for improving patient's memory and understanding of health education. Both of them are used by only a small minority of physicians, I suspect, due to time considerations, but if used more routinely, might be time-efficient in the long run. Both would probably add appreciably to the quality of care our patients receive.

1. Write down your recommendations legibly on a sheet of paper (possibly specially printed with a checklist format) for the patient to take home.

2. Take a minute or two to question the patient about his under-

standing (requiring specific answers, not yes or no responses), his attitudes about your recommendations (acceptance, misgivings, rejection), and his intended behavioral changes.

I suspect that poor or nonexistent documentation of patient education efforts in the medical record is a prime roadblock to the long-term continuity of such efforts. Terse catch phrases in the Plan section of progress notes can sustain educational content and process toward favorable patient education outcomes.

Michael A. Crouch, MD
Robert Wood Johnson Fellow in Family Medicine
University of Missouri—Columbia

References

- Schwartz MS: A design for the collection, processing, and analysis of hypertension data. *Bull NY Acad Med* 52: 735, 1976
- The Framingham Study: An epidemiological investigation of cardiovascular disease. Bethesda, Md, National Heart Institute, 1968
- Geyman JP: How effective is patient education? *J Fam Pract* 10:973, 1980

The preceding letter was referred to Dr. Webb who responds as follows:

I appreciate Dr. Crouch's comments. Pill counts and pill bringing behavior were included with diastolic blood pressure to provide a multi-dimensional measure of compliance. However, pill counts and

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pill bringing as isolated measures are less valid, and blood pressure is the most definitive test of the effectiveness of intervention. Accordingly, baseline data were collected only for diastolic blood pressure. Diastolic blood pressure was recorded by both the nurse and the physician at each visit, and averaged.* The diastolic parameter was chosen because diastolic blood pressure is generally considered to

be more closely correlated with organ damage.¹

It is incorrect to conclude that over half (52 percent) of the sample had diastolic blood pressures of 90 mmHg or lower. The baseline blood pressure was an average of the readings at the two visits prior to intervention. At least one of these was greater than 90 mmHg and, based on chart review, all patients had at least a one-year history of poorly controlled hypertension. My study focused on long-term, uncontrolled hypertensive patients which is, after all, the population most in need of improved compliance. The results should not be generalized to other groups of patients, particularly to newly diagnosed patients. The three, monthly, hour-long intervention sessions failed to dem-

onstrate a positive effect. Rather than speculating on the advantages of even more frequent intervention, I prefer to look to other avenues to improve compliance as proposed in the discussion section of my paper.

*Pamela A. Webb, PhD
Division of Family and
Community Medicine
University of California
San Francisco*

*See Reference No. 25: Webb P: The relative effectiveness of patient education and psychosocial counseling in promoting compliance and control among hypertensive patients, thesis. University of Miami, Miami, Fla, 1978

Reference

1. Thorn GW, Adams RD, Braunwald E, et al (eds): Harrison's Principles of Internal Medicine, ed 8. New York, McGraw-Hill, 1977, pp 188, 1305-1307, 1318

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