

# 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 (diazepam/Roche) 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.

### Medical Ethics Teaching To the Editor:

I very much enjoyed Dr. Carson's and Dr. Curry's treatise, "Ethics Teaching on Ward Rounds" (*Carson RA, Curry RW Jr: J Fam Pract 11:59, 1980*).

What troubles me about their discussion is the legal vacuum in which the rounds were made.

In two of their three case histories, the authors discuss making life and death decisions for mentally incompetent patients. On page 60, they note that the prognosis decision "is a medical question best answered by a physician," and that the life prolongation decision "is a personal question best answered by the patient . . . or by a responsible family member if the patient is incompetent."

The accuracy of those statements depends *entirely* upon in which of the 50 states the questions are asked.

I trust that all thanatology teaching stresses that unfortunately the long arm of the law is the only authority for determining if pulling the plug is sound medical practice or negligent homicide.<sup>1</sup>

The leading, published American court expressly endorsing the authors' judgment is New Jersey in the famous decision, *In the Matter*



of Karen Quinlan, in which that state's highest court properly placed medical ethics where it rightly belongs—within the physician-patient-family relationship. As the Quinlan Court stated, to place such responsibility in the courts is a "gratuitous encroachment upon the medical profession's field of competence."

But in the leading contrary decision, the highest court of Massachusetts has demanded that only courts make grave treatment decisions for incompetent patients. In *Superintendent vs Saikewicz*, that state in 1977 ruled that the court and not physicians must make such decisions, in that life and death decisions "are not to be entrusted to any other group . . . no matter how highly motivated or impressively constituted."

The authors stress an "ethicist-attending physician team" for making such awesome judgments. But in at least Massachusetts and the District of Columbia where that approach is contrary to law, the hospital's counsel and risk manager had better join the team.

My prejudice is completely in support of the authors' reverence for the sacred physician-family re-

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Roche Laboratories  
Division of Hoffmann-La Roche Inc.  
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PRO-BANTHINE® (propantheline bromide) Tablets, 7½ mg. and 15 mg.

INDICATION: Pro-Banthine is effective as adjunctive therapy in the treatment of peptic ulcer.

CONTRAINDICATIONS: Glaucoma, obstructive disease of the gastrointestinal tract, obstructive uropathy, intestinal atony, severe ulcerative colitis or toxic megacolon, hiatal hernia associated with reflux esophagitis, unstable cardiovascular adjustment in acute hemorrhage, or myasthenia gravis.

WARNINGS: Heat prostration can occur with use of the drug in hot weather.

Diarrhea, especially in an ileostomy or colostomy patient, may indicate obstruction, and this possibility should be considered before administering Pro-Banthine.

Pro-Banthine may produce drowsiness or blurred vision.

With overdosage, a curare-like action may occur, i.e., neuromuscular blockade leading to muscular weakness and possible paralysis.

Use with caution in patients with severe cardiac disease if an increase in heart rate is undesirable.

Safe use in pregnancy has not been established. Use during pregnancy only when the benefits outweigh any possible risk.

Uncontrolled data derived from marketing experience do not suggest that significant quantities of Pro-Banthine are secreted in breast milk.

Safety and efficacy in children have not been established.

PRECAUTIONS: Varying degrees of urinary hesitancy may be evidenced by patients with prostatic hypertrophy. Urinary retention may be avoided if such patients are advised to micturate before taking the medication.

Use with caution in the elderly and in all patients with autonomic neuropathy, hepatic or renal disease, hyperthyroidism, coronary heart disease, congestive heart failure, cardiac tachyarrhythmias, or hypertension.

Large doses should be avoided or the drug discontinued in patients with ulcerative colitis.

ADVERSE REACTIONS: Varying degrees of drying of salivary secretions may occur as well as decreased sweating, blurred vision, mydriasis, cycloplegia, and increased ocular tension. Other reported adverse reactions include urinary hesitancy and retention, tachycardia, palpitations, loss of the sense of taste, headache, nervousness, mental confusion, drowsiness, weakness, dizziness, insomnia, nausea, vomiting, constipation, bloated feeling, impotence, suppression of lactation, and allergic reactions or drug idiosyncrasies including anaphylaxis, urticaria and other dermal manifestations.

OVERDOSAGE: The symptoms of Pro-Banthine overdosage include CNS disturbances, circulatory changes, respiratory failure, paralysis and coma. See complete prescribing information for appropriate treatment.

DOSAGE AND ADMINISTRATION: The usual initial adult dose of Pro-Banthine tablets is 15 mg. taken 30 minutes before each meal and 30 mg. at bedtime (a total of 75 mg. daily). Subsequent dosage adjustment should be made according to the patient's individual response and tolerance.

The administration of one 7½-mg. tablet three times a day is convenient for patients with mild manifestations and for geriatric patients and for those of small stature.

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**SEARLE**

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lation. But the student-physician must be acutely aware of the purely legal context in which medical ethics are learned and applied. Otherwise, the physician may find the local probate court judge breathing hotly down his/her white coat.

*Douglas Savage  
Counselor at Law  
Springfield, Ohio*

### Reference

1. Savage D: After *Quinlan* and *Saikewicz*: Death, life, and God committees. *Crit Care Med* 8(2):87, 1980

## Hospital Practice of Family Physicians

To the Editor:

The article by Slabaugh, Ringiewicz, and Babineau, "The Hospital Work of a Family Practice Group in a Medium Size Community in New England" (*J Fam Pract* 11:287, 1980), provides an interesting analysis of inpatient family practice care in a private practice community setting.

The percentage of consultation in their study of 13.7 percent of 997 admissions reflects what I would expect in a community hospital primary care setting. The 57.9 percent rate of consultation reported by Dr. Medley and myself in our review of a residency inpatient service reflects the care of surgical patients by the family physician with consultations having been obtained for procedures such as myelograms and laminectomies.<sup>1</sup> Also, our consultation rate of 46.5 percent of medicine patients was largely due to procedural consultations for cardiology, pulmonary, and gastroenterology service. Dr. Slabaugh's data did not include surgical pa-

tients as these were transferred to primary management by appropriate specialists, thus keeping their percentage of consultation figures at a lower level. Our pediatric consultation rate of only 16.1 percent probably represents a figure reflective of the primary care type setting as these patients for the most part had diagnoses that did not require specialty procedural consultation.

Further distinction in the two studies is that ours was done within a teaching hospital and many of our consultations were often obtained for teaching purposes.

At this time, we unfortunately have no way of separating out our data for each medical condition for the ratio of ambulatory encounters per admission, but I do agree this is the most valid way of assessing an admission ratio.

*Michael L. Halstead, MD, MAJ,  
MC  
Clinical Instructor, Department  
of Family Practice  
Madigan Army Medical Center  
Tacoma, Washington*

### Reference

1. Medley ES, Halstead ML: A family practice residency inpatient service: A review of 631 admissions. *J Fam Pract* 6:817, 1978

## Management of Urinary Tract Infections

To the Editor:

As a 20-year general practice physician, I must take sharp exception to several concepts and statements made by Dr. Jack Froom in his lead article of the September 1980 *Journal of Family Practice* entitled, "The Spectrum of Urinary Tract Infections in Family Practice" (11:385, 1980). He states "The

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**SYNTHROID®**  
(Levothyroxine Sodium Tablets, USP)  
FLINT

**Indications**  
SYNTHROID (levothyroxine sodium) Tablets serve as specific replacement therapy for reduced or absent thyroid function of any etiology.

**Contraindications**  
Relative contraindications include acute myocardial infarction, uncorrected adrenal insufficiency and thyrotoxicosis. (See WARNINGS)

**Warnings**  
Drugs with thyroid hormone activity, alone or together with other therapeutic agents, have been used for the treatment of obesity. In euthyroid patients, doses within the range of daily hormonal requirements are ineffective for weight reduction. Larger doses may produce serious or even life threatening manifestations of toxicity, particularly when given in association with sympathomimetic amines such as those used for their anorectic effects.

Patients with cardiovascular diseases warrant particular attention. In such cases, low initial dosage increased slowly by small increments is indicated. Occasionally, the cardiovascular capacity of the patient is so compromised that the metabolic demands of the normal thyroid state cannot be met. Clinical judgment will then dictate either a partial restoration of thyroid status or reduction in thyroid dosage. Symptoms associated with diabetes mellitus, adrenal insufficiency (Addison's disease), hypopituitarism and diabetes insipidus may be diminished or obscured by hypothyroidism. SYNTHROID (levothyroxine sodium) therapy may aggravate the intensity of previously obscured symptoms and require appropriate adjustment of therapeutic measures directed at these concomitant disorders. Thyroid replacement may potentiate the effects of anticoagulants. Such patients should have frequent prothrombin determinations to assess the need to reduce anticoagulant dosage.

**Precautions**  
Overdosage with any thyroid drug may produce the signs and symptoms of thyrotoxicosis. With SYNTHROID (levothyroxine sodium) Tablets, the relatively slow onset of action minimizes the risk of overdose but close observation in the weeks following institution of a dosage regimen is advised. Treatment of thyroid hyperactivity induced by oral medication is confined to interruption of therapy for a week, followed by reinstitution of daily therapy at an appropriately reduced dosage.

The 100 mcg (0.1 mg) and 300 mcg (0.3 mg) tablets of SYNTHROID (levothyroxine sodium) contain FD & C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible individuals. Although the overall incidence of FD & C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

**Adverse reactions**  
Adverse reactions are due to overdose and are those of induced hyperthyroidism.

**Dosage and administration**  
A final adult dosage of 100 mcg (0.1 mg) to 200 mcg (0.2 mg) of SYNTHROID (levothyroxine sodium) Tablets daily will usually restore normal thyroid function.

The concomitant appearance of other diseases, especially cardiovascular diseases, usually dictates a replacement regimen with initial doses smaller than 100 mcg/day (0.1 mg). In otherwise healthy adults with relatively recent onset of hypothyroidism, full replacement dose of 150 mcg (0.15 mg) or 200 mcg (0.2 mg) has been instituted immediately without untoward effect and with good therapeutic response. However, in view of the possible presence of subclinical disorders of the cardiovascular system or endocrinopathies, a more cautious approach is recommended.

In the elderly patient with long standing disease, evidence of myxedematous infiltration and symptomatic, functional or electrocardiographic evidence of cardiovascular dysfunction, the starting dose may be as little as 25 mcg (0.025 mg) per day. Further incremental increases of 25 mcg (0.025 mg) per day may be instituted at three to four week intervals depending on patient response. Conversely, otherwise healthy adults may be started at higher daily dosage and raised to the full replacement dosage in two to three weeks.

In infants and children, the following dose/kg schedule is recommended: 1-6 months, 10 µg/kg; 6-12 months, 8 µg/kg; 1-5 years, 6 µg/kg; 5-10 years, 4 µg/kg; 10-15 years, 3 µg/kg; 15-20 years, 2.5 µg/kg.

**How supplied**  
SYNTHROID (levothyroxine sodium) Tablets are supplied as scored, color-coded tablets in 6 concentrations: 25 mcg (0.025 mg)—orange... 50 mcg (0.05 mg)—white... 100 mcg (0.1 mg)—yellow... 150 mcg (0.15 mg)—blue... 200 mcg (0.2 mg)—pink... 300 mcg (0.3 mg)—green.  
8-19-19-426AA October 1980

**Reference:**  
1. Wartofsky L, Burman KD: Hypothyroidism, in Conn HF (ed): *Current Therapy*. Philadelphia, WB Saunders Company, 1979, pp 469-473.

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diagnosis requires the demonstration of more than 100,000 bacteria colonies per ml in a freshly voided specimen." And also "Asymptomatic bacteriuria need not be diagnosed or treated except in pregnant women."

I do a culture screen on a mid-stream urine from both male and female patients when proteinuria or pyuria are present regardless of symptomatology, and have found repeatedly more than 100,000 colony count of *Escherichia coli* or other pathogenic organisms. I treat individuals who have minor dysuria with minimal pyuria and no proteinuria with colony counts of less than 100,000 and often find after one week of treatment pronounced pyuria as well as white blood cells and hyaline casts.

The most common cause of urinary infection in female children is poor toilet technique. Children wipe from the anus forward over the perineum, thereby contaminating the introitus with entrance into the urethra with *E coli* organisms; women accomplish the same contamination using pads for menses. The most common cause of cystitis in the adult female is undoubtedly intercourse because of scraping of bacteria off of the skin into the opening of the urethra during thrusting. I certainly do not tell women to stop having intercourse since they would not follow such instructions anyway. I advise them to urinate within 15 minutes after intercourse to wash the organisms out of the urethra.

I have never found any evidence to indicate that voluntary avoidance of urination and the distention of the bladder is responsible for infection in any way. On the contrary, individuals who require frequent voiding during the day and awaken sev-

eral times during the night are much more apt to have infection because of urethral stenosis. Contrary to Dr. Kunin's statement, I feel that urethral instrumentation is important for those individuals who have persistent or recurring urinary infection; when it is found that the urethra is constricted to less than 25 French caliber, dilatation on a bi-monthly basis should be performed until the urethra remains dilated to more than 30 fr.

Every physician who sees patients for urinary infections should do a microscopic urinalysis, perform screening cultures of pyuria but not bacteriuria, and be able to do a diagnostic-therapeutic urethral dilatation when indicated.

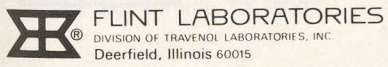
There is no disagreement that "asymptomatic" bacterial endocarditis should be vigorously treated because of possible sequelae, and I feel that the kidneys are just as important for long-term health.

*Richard Hopkins, MD  
Columbus, North Carolina*

*The preceding letter was referred to Dr. Froom, who responds as follows:*

I appreciate Dr. Hopkin's careful reading of my article entitled "The Spectrum of Urinary Tract Infections in Family Practice" (*J Fam Pract* 11:385, 1980) and his thoughtful comments. The criterion of 100,000 colonies of bacteria per ml of urine as a requirement for the diagnosis of urinary tract infection is based on observations by Kass that 95 percent of cases of clinical pyelonephritis had counts which exceeded that number. In his series most contaminated specimens grew

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out less than 10,000 colonies. These figures appear to have been widely adopted as criteria for the diagnosis of urinary tract infection. In an article published concurrently with mine, however, Dr. Stamm et al report that infection may be present in women with the acute urethral syndrome with counts of less than 100,000.<sup>1</sup>

I agree that fecal contamination of the vaginal introitus can contribute to urinary tract infection and that sexual intercourse may be an additional etiological factor. At least one study, however (Buckley et al, Ref. No. 22), failed to demonstrate the therapeutic value of post-coital voiding. Dr. Hopkins may wish to refer to work by Lapides (Ref. No. 20) and Adatto (Ref.

No. 21) concerning evidence that over-distension of the urinary bladder and voluntary avoidance of urination are important pathogenic mechanisms. Studies quoted in my article failed to show any benefit or even a rational basis for urethral dilatations to prevent recurrent infection. I would encourage Dr. Hopkins to furnish evidence to the contrary, either by personal research or citations of research done by others. Likewise, after many therapeutic long-term trials, there is no evidence that the therapy of asymptomatic bacteriuria confers any benefit to the patient. It appears obvious to me, at least, that asymptomatic bacterial endocarditis is not comparable with asymptomatic bacteriuria.

Ours is a difficult discipline composed of a mixture of both art and

science. Having spent 21 years in private practice and ten years in an academic setting, I realize that scientific information changes with time. Nevertheless, it is necessary to use the best data available at any given time. It is incumbent on physicians who use methods such as urethral dilatation, which can be both painful and expensive for our patients, to justify such therapy with information that is more than anecdotal.

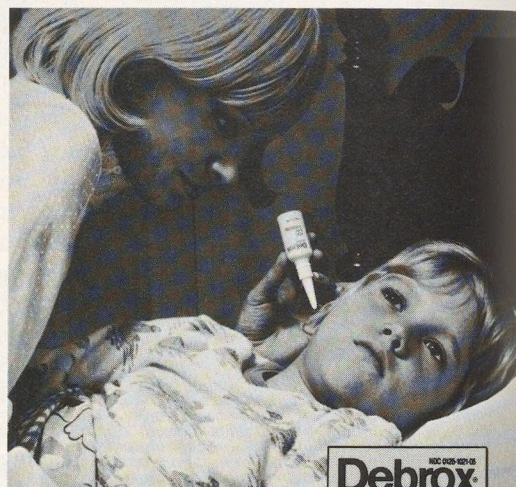
*Jack Froom, MD  
Professor of Family Medicine  
State University of New York at  
Stony Brook*

**Reference**

1. Stamm WE, Wagner KF, Amsel R, et al: Causes of the acute urethral syndrome in women. *N Engl J Med* 303:409, 1980

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