

As an adjunct to rest and physical therapy

ROBAXIN®-750

(Methocarbamol Tablets, USP), 750 mg

ROBAXISAL®

Methocarbamol, USP, 400 mg/Aspirin, USP, 325 mg

INDICATIONS: Robaxin-750 and Robaxisal are indicated as adjuncts to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions.

The mode of action of methocarbamol has not been clearly identified, but may be related to its sedative properties. Methocarbamol does not directly relax skeletal muscles in man.

CONTRAINDICATIONS: Hypersensitivity to methocarbamol or aspirin.

WARNINGS: Since methocarbamol may possess a general central nervous system depressant effect, patients receiving Robaxin-750 or Robaxisal should be cautioned about combined effects with alcohol and other CNS depressants.

PRECAUTIONS: Products containing aspirin should be administered with caution to patients with gastritis or peptic ulceration, or those receiving hypoprothrombinemic anticoagulants.

Methocarbamol may cause a color interference in certain screening tests for 5-hydroxyindoleacetic acid (5-HIAA) and vanilmandelic acid (VMA).

Pregnancy: Safe use of Robaxin-750 and Robaxisal has not been established with regard to possible adverse effects upon fetal development. Therefore, Robaxin-750 or Robaxisal should not be used in women who are or may become pregnant and particularly during early pregnancy unless in the judgment of the physician the potential benefits outweigh the possible hazards.

Nursing Mothers: It is not known whether methocarbamol is secreted in human milk; however, aspirin does appear in human milk in moderate amounts. It can produce a bleeding tendency either by interfering with the function of the infant's platelets or by decreasing the amount of prothrombin in the blood. The risk is minimal if the mother takes the aspirin just after nursing and if the infant has an adequate store of vitamin K. As a general rule, nursing should not be undertaken while a patient is on a drug.

Pediatric Use: Safety and effectiveness in children 12 years of age and below have not been established.

Use in Activities Requiring Mental Alertness: Robaxisal may rarely cause drowsiness. Until the patient's response has been determined, he should be cautioned against the operation of motor vehicles or dangerous machinery.

ADVERSE REACTIONS: The most frequent adverse reaction to methocarbamol is dizziness or lightheadedness and nausea. This occurs in about one in 20-25 patients. Less frequent reactions are drowsiness, blurred vision, headache, fever, allergic manifestations such as urticaria, pruritus, and rash.

Adverse reactions that have been associated with the use of aspirin include: nausea and other gastrointestinal discomfort, gastritis, gastric erosion, vomiting, constipation, diarrhea, angio-edema, asthma, rash, pruritus, urticaria.

Gastrointestinal discomfort may be minimized by taking Robaxisal with food.

DOSE AND ADMINISTRATION: Robaxin-750:

Adults: Initial dosage, 2 tablets q.i.d.; maintenance dosage, 1 tablet q.4h. or 2 tablets i.i.d. Six grams a day are recommended for the first 48 to 72 hours of treatment. (For severe conditions 8 grams a day may be administered.) Thereafter, the dosage can usually be reduced to approximately 4 grams a day.

Robaxisal: Adults and children over 12 years of age: Two tablets four times daily. Three tablets four times daily may be used in severe conditions for one to three days in patients who are able to tolerate salicylates. These dosage recommendations provide respectively 3.2 and 4.8 grams of methocarbamol per day.

OVERDOSAGE: Toxicity due to overdosage of methocarbamol is unlikely; however, acute overdosage of aspirin may cause symptoms of salicylate intoxication.

Treatment of Overdosage: Supportive therapy for 24 hours, as methocarbamol is excreted within that time. If salicylate intoxication occurs, especially in children, the hyperpnea may be controlled with sodium bicarbonate. Judicious use of 5% CO₂ with 95% O₂ may be of benefit. Abnormal electrolyte patterns should be corrected with appropriate fluid therapy.

HOW SUPPLIED: Robaxin-750 is supplied as white capsule-shaped tablets in bottles of 100 (NDC 0031-7449-63) and 500 (NDC 0031-7449-70) and Dis-Co® Unit Dose Packs of 100 (NDC 0031-7449-64).

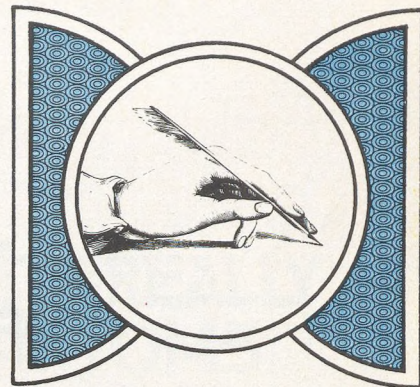
Robaxisal is supplied as pink and white laminated, compressed tablets in bottles of 100 (NDC 0031-7469-63) and 500 (NDC 0031-7469-70) and Dis-Co® Unit Dose Packs of 100 (NDC 0031-7469-64).

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A.H. ROBINS

A.H. Robins Company, Richmond, Va. 23220

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.

Evaluating Curriculum Effectiveness

To the Editor:

Teachers of family medicine who try to assess the effectiveness of their curriculum often find it impossible to apply rigorously standard evaluation designs such as those described by Campbell and Stanley¹ when faced with the "rumpled reality" of teaching. This communication describes a quick and simple measure we have used to evaluate curriculum effectiveness in order to adjust resources and shift emphasis.

The Section of Family Medicine at Brown University conducts a required six-week clerkship in family medicine and community health for third and fourth year medical students. An oral examination using preestablished criteria² is used as part of the final evaluation.

In January 1980 a case study was used that tested the students' knowledge of the diagnosis and treatment of alcoholism. Of the eight students taking the oral examination, only one diagnosed alcoholism as a problem, and none of the eight confronted the patient with the problem.

Because of our concern about the lack of sensitivity to the diagnosis of alcoholism, 5.5 hours of didactic and experiential teaching

in alcoholism were incorporated in the clerkship.

The same oral examination case study was repeated in April 1981. All seven of the students taking the oral examination diagnosed alcoholism as the chief problem. Six of the seven students forcefully confronted the patient with his problem drinking. The difference in these two criteria are significantly different as compared to the January 1980 performance based on the nonparametric sign test ($P = 0.016$, one-tailed binomial test for each of the two major criteria).

Based on the results of this quick evaluation, we felt reasonably comfortable concluding that the curriculum intervention was successful. In addition, despite the fairly brief 5.5-hour intervention, it was felt that this might be sufficient.

The advantages of this design are simplicity, quick results, and utility. It allows the curriculum planner to quickly assess whether the intervention has been successful, although this is only one of several explanations for the observed improvement.

The disadvantages of this static group comparison design include the failure to take into account differences between the control and the experimental group, interven-

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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. Anxiety or tension associated with the stress of everyday life usually does not require treatment with an anxiolytic. 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 antidepressants 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. The clearance of Valium and certain other benzodiazepines can be delayed in association with Tagamet (cimetidine) administration. The clinical significance of this is unclear.

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).

How Supplied: For oral administration, Valium scored tablets—2 mg, white; 5 mg, yellow; 10 mg, blue—bottles of 100* and 500.* Prescription Packs of 50, available in trays of 10.* Tel-E-Dose* packages of 100, available in trays of 4 reverse-numbered boxes of 25,† and in boxes containing 10 strips of 10.‡

*Supplied by Roche Products Inc., Manati, Puerto Rico 00701

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

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ing factors between the two periods of time, nonrandom assignment of individuals to the two groups, and possible bias in the examiners.

In no way does this design substitute for the more rigorous experimental or quasiexperimental reresearch designs. However, the latter are often too cumbersome to use to meet the day-to-day needs of a teacher, and the approach described above should be seriously considered by family medicine educators.

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References

1. Campbell DT, Stanley JC: Experimental and Quasiexperimental Designs for Research. Chicago, Rand McNally, 1972
2. Holcomb JD, Garner AE: Improving Teaching in Medical Schools. Springfield, Illinois, Charles C Thomas, 1973

Simultaneous Influenza and Pneumococcal Vaccination

To the Editor:

In the August issue of this Journal appeared "Adverse Reactions to Simultaneous Influenza and Pneumococcal Vaccination" (*J Fam Pract* 13: 175, 1981) in which the author, Dr. McCue, concluded, "Simultaneous administration of pneumococcal and influenza vaccines consistently caused more side effects than either vaccine alone, although all the differences were quite small."

This study suffers from a complete avoidance of statistical analysis to support the author's conclusion. Furthermore, cursory examination of the results shows additive inci-

dences of side effects by receiving pneumococcal influenza shots on separate visits exceeds that of receiving them together. Here again, statistical analyses should be employed for this only adds further credence to the tenet that both vaccines be given concomitantly.

Robert J. Creager, MD
Assistant Director
Family Practice Residency
Program
Scottsdale Memorial Hospital
Scottsdale, Arizona

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

I agree entirely with Dr. Creager's comments. Statistical data were omitted, since on simple inspection of the data no statistical difference is evident. How important statistical analysis is in a study such as this is, moreover, unclear. Other studies cited in the article support the conclusion that simultaneous vaccination increases the incidence of side effects slightly but probably not significantly. I agree with the conclusion that in most circumstances both vaccines should be given concomitantly.

Jack D. McCue, MD
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Patient Acceptance of Physicians' Assistants

To the Editor:

We were pleased to note continuing documentation of physician assistant patient acceptance in the article "Patient Attitudes toward Physicians' Assistants" (*J Fam Pract* 13: 201, 1981). It was espe-

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cially gratifying to learn that in this study 92 percent of the sample was usually or always satisfied with physicians' assistants' care.

Despite this positive finding, we were concerned with the general negative tone that permeates the article. We were particularly troubled by the implication that the use of a physician's assistant invites

some inevitable discomfort for patients. Research on the quality of care provided by physicians' assistants and nurse practitioners in an ambulatory setting when a physician is present has been found to be equal to that provided by fully trained physicians.^{1,2}

I hope this article will be carefully read by family physicians so that its positive findings will be ap-

parent. We think it unfortunate that these were not emphasized more in the article.

Joseph G. Daddabbo, PA
W. Ward Patrick, MD

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References

1. Sox HC: Quality of patients care by nurse practitioners and physician's assistants: A ten-year perspective. *Ann Intern Med* 91:459, 1979

2. Goldberg GA, Jolly DG: Quality of care provided by physician's extenders in Air Force primary medicine clinics. Santa Monica, Calif, Rand Corporation, 1981

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

I feel that it is unfortunate that Mr. Daddabbo and Dr. Patrick feel that the article conveys a negative tone. The central point is that patients are satisfied with physicians' assistants *provided* they are adequately supervised and that the patients are convinced that this supervision exists. While it is clear that there is high acceptance of physicians' assistants, the primary point I wish to make is that this acceptance is more likely to occur within the limitations that are discussed in the article, that is, that the supervision exists and that the physicians' assistants are functioning in a role that the patients interpret as an appropriate role (providing routine functions, health information, and physical examinations as opposed to diagnostic and treatment encounters). There was concern expressed about the implication that the use of physicians' assistants invites discomfort for patients; however, it should be noted that 29 percent of the patients in the study were at least oc-

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BRIEF SUMMARY

MINIPRESS® (prazosin hydrochloride) CAPSULES For Oral Use

INDICATIONS: MINIPRESS® (prazosin hydrochloride) is indicated in the treatment of hypertension. As an antihypertensive drug, it is mild to moderate in activity. It can be used as the initial agent or it may be employed in a general treatment program in conjunction with a diuretic and/or other antihypertensive drugs as needed for proper patient response.

WARNINGS: MINIPRESS (prazosin hydrochloride) may cause syncope with sudden loss of consciousness. In most cases this is believed to be due to an excessive postural hypotensive effect, although occasionally the syncopal episode has been preceded by a bout of severe tachycardia with heart rates of 120-160 beats per minute. Syncopal episodes have usually occurred within 30 to 90 minutes of the initial dose of the drug; occasionally they have been reported in association with rapid dosage increases or the introduction of another antihypertensive drug into the regimen of a patient taking high doses of MINIPRESS (prazosin hydrochloride). The incidence of syncopal episodes is approximately 1% in patients given an initial dose of 2 mg or greater. Clinical trials conducted during the investigational phase of this drug suggest that syncopal episodes can be minimized by limiting the initial dose of the drug to 1 mg, by subsequently increasing the dosage slowly, and by introducing any additional antihypertensive drugs into the patient's regimen with caution (see **DOSAGE AND ADMINISTRATION**). Hypotension may develop in patients given MINIPRESS who are also receiving a beta-blocker such as propranolol.

If syncope occurs, the patient should be placed in the recumbent position and treated supportively as necessary. This adverse effect is self-limiting and in most cases does not recur after the initial period of therapy or during subsequent dose titration.

Patients should always be started on the 1 mg capsules of MINIPRESS (prazosin hydrochloride). The 2 and 5 mg capsules are not indicated for initial therapy.

More common than loss of consciousness are the symptoms often associated with lowering of the blood pressure, namely, dizziness and lightheadedness. The patient should be cautioned about these possible adverse effects and advised what measures to take should they develop. The patient should also be cautioned to avoid situations where injury could result should syncope occur during the initiation of MINIPRESS (prazosin hydrochloride) therapy.

Usage in Pregnancy: Although no teratogenic effects were seen in animal testing, the safety of MINIPRESS (prazosin hydrochloride) in pregnancy has not been established. MINIPRESS (prazosin hydrochloride) is not recommended in pregnant women unless the potential benefit outweighs potential risk to mother and fetus.

Usage in Children: No clinical experience is available with the use of MINIPRESS (prazosin hydrochloride) in children.

ADVERSE REACTIONS: The most common reactions associated with MINIPRESS (prazosin hydrochloride) therapy are: dizziness 10.3%, headache 7.8%, drowsiness 7.6%, lack of energy 6.9%, weakness 6.5%, palpitations 5.3%, and nausea 4.9%. In most instances side effects have disappeared with continued therapy or have been tolerated with no decrease in dose of drug.

The following reactions have been associated with MINIPRESS (prazosin hydrochloride), some of them rarely. (In some instances exact causal relationships have not been established.)

Gastrointestinal: vomiting, diarrhea, constipation, abdominal discomfort and/or pain.

Cardiovascular: edema, dyspnea, syncope, tachycardia.

Central Nervous System: nervousness, vertigo, depression, paresthesia.

Dermatologic: rash, pruritus, alopecia, lichen planus.

Genitourinary: urinary frequency, incontinence, impotence, priapism.

EENT: blurred vision, reddened sclera, epistaxis, tinnitus, dry mouth, nasal congestion.

Other: diaphoresis.

Single reports of pigmentary mottling and serous retinopathy, and a few reports of cataract development or disappearance have been reported. In these instances, the exact causal relationship has not been established because the baseline observations were frequently inadequate.

In more specific slit-lamp and fundoscopic studies, which included adequate baseline examinations, no drug-related abnormal ophthalmological findings have been reported.

DOSAGE AND ADMINISTRATION: The dose of MINIPRESS (prazosin hydrochloride) should be adjusted according to the patient's individual blood pressure response. The following is a guide to its administration:

Initial Dose: 1 mg two or three times a day. (See Warnings.)

Maintenance Dose: Dosage may be slowly increased to a total daily dose of 20 mg given in divided doses. The therapeutic dosages most commonly employed have ranged from 6 mg to 15 mg daily given in divided doses. Doses higher than 20 mg usually do not increase efficacy, however a few patients may benefit from further increases up to a daily dose of 40 mg given in divided doses. After initial titration some patients can be maintained adequately on a twice daily dosage regimen.

Use With Other Drugs: When adding a diuretic or other antihypertensive agent, the dose of MINIPRESS (prazosin hydrochloride) should be reduced to 1 mg or 2 mg three times a day and retitration then carried out.

HOW SUPPLIED: MINIPRESS (prazosin hydrochloride) is available in 1 mg (white #431), 2 mg (pink and white #437) capsules in bottles of 250, 1000, and unit dose institutional packages of 100 (10 x 10's); and 5 mg (blue and white #438) capsules in bottles of 250, 500 and unit dose institutional packages of 100 (10 x 10's).

More detailed information available on request.



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casionaly uncomfortable with physicians' assistants or had had unsatisfactory physician's assistant visits. The statement was not intended to imply that there was inevitable discomfort for all patients who see physicians' assistants. The statement was made that research shows the quality of care provided by physicians' assistants is equal to that of fully trained physicians. It should be noted that we did not attempt in this study to look at quality of care, but only at patient satisfaction. Patients are sometimes dissatisfied with the health care encounters, even if the care is of the highest quality.

While it is true that the article reports on high patient acceptance of physicians' assistants, it would be a mistake to leave the data at that point. I would disagree with the statement that controversy, emotional reaction, and confusion surrounding the use of physicians' assistants is not documented in this study. Questions dealing with the issue of uncomfortable visits with physicians' assistants, patients going elsewhere for health care because of seeing physicians' assistants, and frankly negative reactions to physicians' assistants certainly deal with the question of emotional reactions to them. The area of confusion with the use of physicians' assistants is documented in the section of the article reporting on patients' perception of the role in training a physician's assistant. It is clear from the data that many patients are confused about the role and training of the physician's assistant.

In summary, I believe the data in this study support the use of physicians' assistants but suggest that patients feel that their role should be better defined to patients, that

they should be closely supervised by physicians, and that their role should be largely limited to routine functions. This does not in any way suggest that physicians' assistants do not deliver high quality medical care. Certainly more data on the role of physicians' assistants in health care are needed and would be welcome.

Charles W. Smith, Jr, MD
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Extended Tip Spatula for Cervical Cytology

To the Editor:

I was interested in the article "The Extended Tip Spatula for Cervical Cytology," by V.F. Colon and L.E. Linz (*J Fam Pract* 13:37, 1981). It is of interest that the literature concerning the use of cotton tipped applicator swabs for the recovery of endocervical specimens for cytologic examination has been well covered, and it is the recommendation of many cytopathologists that this represents a suboptimal method. It is hoped that the introduction of the extended tip spatula will obviate continued discourse concerning the cotton tipped applicators. Dr. Rubio from the Karolinska in Stockholm has commented on this issue most recently in *The Lancet*.

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Reference

1. Rubio CA: "False-negative smears" in gynaecological cytology. *Lancet* i:979, 1979