

Minipress® B.I.D. Dosage (prazosin HCl) Convenience

Capsules 1mg, 2mg, 5mg

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 funduscopic 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.

References: 1. O'Conner DJ, Preston RA, Sasso EH: Renal perfusion changes during treatment of essential hypertension: Prazosin versus propranolol. *J Cardiovasc Pharmacol* 1(suppl):S38-S42, 1979. 2. Falase AO, Salako LA: The effect of prazosin combined with a diuretic, polythiazide, in hypertensive Africans. *Curr Ther Res* 25:10-15, 1979. 3. Okun R, Maxwell M: Long-term antihypertensive therapy with prazosin plus a diuretic. *J Cardiovasc Pharmacol* 1(suppl):S21-S27, 1979. 4. Kirkendall WM, Hammond JJ, Thomas JC, et al: Prazosin and clonidine for moderately severe hypertension. *JAMA* 240 (23): 2553-2556, December 1, 1978. 5. Harter HR, Delmeze JA: Effects of prazosin in the control of blood pressure in hypertensive dialysis patients. *J Cardiovasc Pharmacol* 1(suppl):S43-S55, 1979. 6. Leren P, Foss PO, Helgeland A, et al: Effect of propranolol and prazosin on blood lipids: The Oslo study. *Lancet*: 4-6, July 5, 1980. 7. Lowenstein J, Neusy A-J: The biochemical effects of antihypertensive agents and the impact on atherosclerosis. *J Cardiovasc Pharmacol* 4 (suppl 2):S262-S264, 1982. 8. Kokubu T, Itoh I, Kurita H, et al: Effect of prazosin on serum lipids. *J Cardiovasc Pharmacol* 4 (suppl 2):S228-S232, 1982. 9. Velasco M, Silva H, Morillo J, et al: Effect of prazosin on blood lipids and on thyroid function in hypertensive patients. *J Cardiovasc Pharmacol* 4 (suppl 2):S225-S227, 1982.

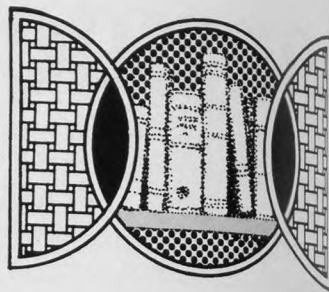
Book Reviews

Pediatric Orthopedics in Clinical Practice. Peter V. Scoles. Year Book Medical Publishers, Chicago, 1982, 241 pp., \$74.50.

The author states in his preface that his intent is to provide a "practical guide to common musculoskeletal disorders" rather than a comprehensive text of pediatric orthopedics. He does succeed in covering in rather succinct fashion most of the acute and chronic orthopedic problems of children likely to be encountered in family practice. The text is well written, and the illustrations are both clear and pertinent.

As is often the case when specialists write books for use in family practice, the emphasis of some sections is not always on the points likely to raise questions and cause the family physician to open the book in the first place. Pathophysiology and diagnosis are well covered, but therapy is dealt with briefly and usually dichotomized into those cases with very straightforward management and those that should be referred. Toenail excisions and mallet finger splinting are two examples of relatively simple procedures for which the author provides little advice other than to refer to a specialist.

Because of its breadth of coverage, this book is more suited for reference than for weekend reading. It would be appropriate for residents or practicing physicians wishing to review the pathophysiology or diagnosis of conditions



presenting in the office; however, I found the lack of depth regarding therapy a limitation to the book's overall usefulness.

Fred Heidrich, MD
Seattle, Washington

Basic Neurology. John Gilroy, Patti L. Holliday. The MacMillan Company, New York, 1982, 373 pp., \$18.95 (paper).

This book is directed primarily at medical students and residents in neurology and other specialties in which neurological problems are frequently encountered. The combined authorship of John Gilroy, a senior neurologist, and Patti Holliday, a resident in neurology, addresses successfully many of the potential problems of writing such a text. Comprehensive and authoritative, the book covers a broad range of neurological conditions, including the rare ones the resident will surely encounter in a residency program. At the same time it is very readable and maintains a good balance of basic science, clinical findings and diagnosis, and therapy.

Some discussion of rare events, such as certain congenital syndromes, are of little relevance to a family physician; however, some of the content is very useful. The discussion of the neurological examination is a good review and includes reference to common dysfunctions. Other chapters that I find particularly good include as-

assessment of the comatose patient, diagnosis and management of seizure disorders, and headaches. The chapter on tumors provides an excellent table of signs associated with lesions in specific areas of the brain. Some discussion concerns fairly recent developments such as the neurological complications of dialysis and neurological complications of patients with Hodgkin's disease and leukemia.

I think the book is a very useful reference book for the family physician.

*John R. Hilditch, MD
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Toronto, Ontario*

Patients and Healers in the Context of Culture: An Exploration of the Borderland Between Anthropology, Medicine, and Psychiatry. Arthur Kleinman. Berkeley, University of

California Press, 1980, 427 pp., \$29.50 (\$9.95 paperback).

This book examines the interrelationship between culture and health care from the broad perspectives of medicine, medical anthropology, and psychiatry. Kleinman advances a compelling ecological model of health care systems. Using extensive field data from personal observation and interviews of patients, families, clinicians, and other healers in the United States and Taiwan, he explains the "inner workings of clinical care" and synthesizes "explanatory models" of patients and healers in diverse settings. These define relationships between healers and their patients. He illustrates the importance of entering their cultural framework to achieve an understanding of the "clinical reality" of each.

The writing is scholarly, richly

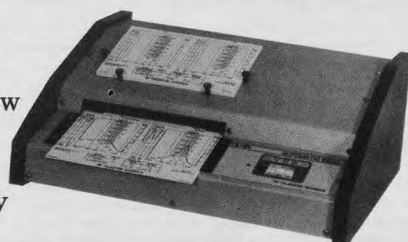
referenced, and thought provoking. The book deserves a commitment from the reader, who will be well rewarded. What might seem to have limited relevance to the practice of medicine in the United States in fact provides an opportunity to identify and analyze illness experiences, patient-physician transactions, and the healing process from a psychosociocultural standpoint. His conceptualization of medicine as a social and cultural system and discussions of interacting popular, folk, and professional sectors of care with patients entering and leaving at boundary interfaces are especially pertinent to the family physician and generally instructive to all individuals involved in the care of patients.

*Eugenia English, MD
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