

# Minipress®

(prazosin HCl) 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 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. 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 **DOSE 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 capsule of MINIPRESS. 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 therapy.

**Usage in Pregnancy:** Although no teratogenic effects were seen in animal testing, the safety of MINIPRESS in pregnancy has not been established. MINIPRESS 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 in children.

**ADVERSE REACTIONS:** The most common reactions associated with MINIPRESS 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 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.  
Dermatological: 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.

**DOSE AND ADMINISTRATION:** The dose of MINIPRESS 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 should be reduced to 1 mg or 2 mg three times a day and retitration then carried out.

**OVERDOSAGE:** Accidental ingestion of at least 50 mg of MINIPRESS in a two year old child resulted in profound drowsiness and depressed reflexes. No decrease in blood pressure was noted. Recovery was uneventful.

Should overdose lead to hypotension, support of the cardiovascular system is of first importance. Restoration of blood pressure and normalization of heart rate may be accomplished by keeping the patient in the supine position. If this measure is inadequate, shock should first be treated with volume expanders. If necessary, vasopressors should then be used. Renal function should be monitored and supported as needed. Laboratory data indicate MINIPRESS is not dialysable because it is protein bound.

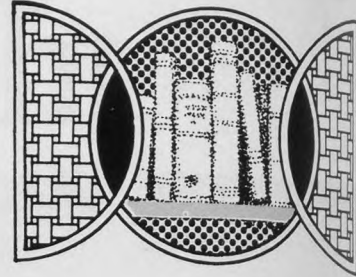
**TOXICOLOGY:** Testicular changes, necrosis and atrophy have occurred at 25 mg/kg/day (60 times the usual maximum recommended dose of 20 mg per day in humans) in long term (one year or more) studies in rats and dogs. No testicular changes were seen in rats or dogs at the 10 mg/kg/day level (24 times the usual maximum recommended dose of 20 mg per day in humans). In view of the testicular changes observed in animals, 105 patients on long term MINIPRESS (prazosin hydrochloride) therapy were monitored for 17-ketosteroid excretion and no changes indicating a drug effect were observed. In addition, 27 males on MINIPRESS (prazosin hydrochloride) alone for up to 51 months did not demonstrate changes in sperm morphology suggestive of drug effect.

**HOW SUPPLIED:** MINIPRESS 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. Lipson LG, Moore D, Pope AM et al: Sexual dysfunction in hypertensive diabetic men. *J Cardiovasc Med* (special suppl), April 1981, pp 30-37. 2. Adapted from Kaplan NM: Summary. *J Cardiovasc Pharmacol* 4 (suppl 2): S265, 1982. 3. Lund-Johansen P: Hemodynamic changes at rest and during exercise in long-term prazosin therapy for essential hypertension, in Prazosin Clinical Symposium Proceedings. Published as a special report by *Postgraduate Medicine*, New York, McGraw-Hill Book and Education Services Group, 1975, pp 45-52. 4. Pitts NE: The clinical evaluation of prazosin, a new antihypertensive agent, in Prazosin Clinical Symposium Proceedings. Published as a special report by *Postgraduate Medicine*, New York, McGraw-Hill Book and Education Services Group, 1975, pp 117-127.

## Book Reviews



**Prevention and Treatment of Running Injuries.** Robert D'Ambrosia, David Drez, Jr. Charles B. Slack, Thorofare, New Jersey, 1982, 204 pp., price not available.

According to its cover leaf this book is written as a resource for "any orthopedic surgeon, general practitioner, therapist, or coach who deals with running injuries on a daily basis." The scope is fairly narrow, as indicated by the title; thus, this would not serve as a general sports medicine text, nor does it deal with all the medical aspects of running. Nevertheless, many of the chapters, such as those on stretching and nutrition, could be applied to many sports.

The book is a series of monographs by 14 authors, each presumably with great expertise in the specific area about which he writes. From a family physician's point of view, it seemed I was often reading how problems are dealt with when they reach a referral center, rather than how I may wish to deal with them in my office.

Numerous illustrations are used, at times more than seemed warranted. The small size of many operative photographs and figures compromised their interpretability, and figures were often several pages distant from the relevant text. Typographical errors were surprisingly numerous.

I did find the sections on prevention of injury helpful. I feel that this book would be of some use to the practicing family physician caring for runners, but perhaps would be most useful as a reference text in a sports medicine clinic.

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**Primer of Clinical Psychopharmacology: A Practical Guide.** Donald M. Pirodsky. Medical Examination Publishing Company, Garden City, New York, 1981, 125 pp., \$12.95.

This concise paperback handbook gives an excellent review of clinical psychopharmacology. It is well indexed, very readable, and well organized. The text reviews each major drug group and is specifically broken down into individual drugs, comparing them with similar drugs. The guidelines for clinical use, side effects, and toxic problems with each drug are reviewed. The index is nicely cross-referenced with generic as well as trade names, making it easy to use as a quick handbook for reference in the office. It is an excellent book for medical students, allied health personnel, family practice residents, or those physicians who need a rapid review or update of psychopharmacology.

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