

# Novafed<sup>®</sup> A Capsules

Decongestant Plus Antihistamine  
Controlled-Release

**ACTIONS:** NOVAFED A combines the action of a nasal decongestant, pseudoephedrine hydrochloride, and an antihistamine, chlorpheniramine maleate. These ingredients are combined to provide prompt and sustained nasal and upper respiratory decongestant and antihistaminic action.

Pseudoephedrine hydrochloride is an orally effective nasal decongestant. Pseudoephedrine is a sympathomimetic amine with peripheral effects similar to epinephrine and central effects similar to, but less intense than, amphetamines. It has, therefore, the potential for excitatory side effects. At the recommended oral dosage, pseudoephedrine has little or no pressor effect in normotensive adults. Patients taking pseudoephedrine orally have not been reported to experience the rebound congestion sometimes experienced with frequent, repeated use of topical decongestants.

Chlorpheniramine maleate is an antihistaminic drug which possesses anticholinergic and sedative effects. It is considered one of the most effective and least toxic of the histamine antagonists. Chlorpheniramine antagonizes many of the pharmacologic actions of histamine. It prevents released histamine from dilating capillaries and causing edema of the respiratory mucosa.

**INDICATIONS:** NOVAFED A is indicated for the relief of nasal congestion and eustachian tube congestion associated with the common cold, sinusitis and acute upper respiratory infections. It is also indicated for perennial and seasonal allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis due to inhaled allergens and foods and for mild, uncomplicated allergic skin manifestations of urticaria and angioedema. Decongestants in combination with antihistamines have been used for many years to relieve eustachian tube congestion associated with acute eustachian salpingitis, aerotitis media, acute otitis media and serous otitis media. NOVAFED A may be given concurrently, when indicated, with analgesics and antibiotics.

**CONTRAINDICATIONS:** Sympathomimetic amines are contraindicated in patients with severe hypertension, severe coronary artery disease, hyperthyroidism, and in patients on MAO inhibitor therapy. Antihistamines are contraindicated in patients with narrow-angle glaucoma, urinary retention, peptic ulcer, during an asthmatic attack, and in patients receiving MAO inhibitors.

Children under 12: NOVAFED A controlled-release capsules should not be used in children less than 12 years of age.

Nursing Mothers: Pseudoephedrine is contraindicated in nursing mothers because of the higher than usual risk for infants from sympathomimetic amines.

Hypersensitivity: This drug is contraindicated in patients with hypersensitivity or idiosyncrasy to sympathomimetic amines or antihistamines. Patient idiosyncrasy to adrenergic agents may be manifested by insomnia, dizziness, weakness, tremor or arrhythmias.

**WARNINGS:** Sympathomimetic amines should be used judiciously and sparingly in patients with hypertension, diabetes mellitus, ischemic heart disease, increased intraocular pressure, or prostatic hypertrophy. See, however, Contraindications. Sympathomimetics may produce central nervous system stimulation and convulsions or cardiovascular collapse with accompanying hypotension.

Antihistamines may impair mental and physical abilities required for the performance of potentially hazardous tasks, such as driving a vehicle or operating machinery, and mental alertness in children. Chlorpheniramine maleate has an atropine-like action and should be used with caution in patients with increased intraocular pressure, cardiovascular disease, hypertension or in patients with a history of bronchial asthma. See, however, Contraindications.

Do not exceed recommended dosage.

**Use in Pregnancy:** The safety of pseudoephedrine for use during pregnancy has not been established.

**Use in Elderly:** The elderly (60 years and older) are more likely to have adverse reactions to sympathomimetics. Overdosage of sympathomimetics in this age group may cause hallucinations, convulsions, CNS depression, and death. Therefore, safe use of a short-acting sympathomimetic should be demonstrated in the individual elderly patient before considering the use of a sustained-action formulation.

**PRECAUTIONS:** This drug should be used with caution in patients with diabetes, hypertension, cardiovascular disease and hyperreactivity to epinephrine. The antihistaminic may cause drowsiness and ambulatory patients who operate machinery or motor vehicles should be cautioned accordingly.

**ADVERSE REACTIONS:** Hyperreactive individuals may display epinephrine-like reactions such as tachycardia, palpitations, headache, dizziness, or nausea. Patients sensitive to antihistamines may experience mild sedation.

Sympathomimetic drugs have been associated with certain untoward reactions including fear, anxiety, tenseness, restlessness, tremor, weakness, pallor, respiratory difficulty, dysuria, insomnia, hallucinations, convulsions, CNS depression, arrhythmias, and cardiovascular collapse with hypotension.

Possible side effects of antihistamines are drowsiness, restlessness, dizziness, weakness, dry mouth, anorexia, nausea, headache and nervousness, blurring of vision, heartburn, dysuria and very rarely, dermatitis.

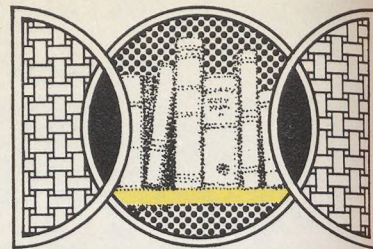
**DRUG INTERACTIONS:** MAO inhibitors and beta adrenergic blockers increase the effect of sympathomimetics. Sympathomimetics may reduce the antihypertensive effects of methyl-dopa, mecamylamine, reserpine and veratrum alkaloids. Concomitant use of antihistamines with alcohol, tricyclic antidepressants, barbiturates and other central nervous system depressants may have an additive effect.

**DOSAGE AND ADMINISTRATION:** One capsule every 12 hours. Do not give to children under 12 years of age.

**CAUTION:** Federal law prohibits dispensing without prescription.

**DOW** DOW PHARMACEUTICALS  
The Dow Chemical Company  
Indianapolis, IN 46268

## Book Reviews



**Drugs of Choice 1976-1977.** Walter Modell (ed). The C.V. Mosby Company, Saint Louis, 1976, 898 pp., \$28.50 (US), \$29.95 (Canada).

This is the tenth edition of a text with multiple contributors which is intended as a practical guide to the selection of the best drug for a particular therapeutic problem. In each of 40 chapters, one or several experts give their opinions as to the drugs of choice for particular problems categorized according to therapeutic classifications. In keeping pace with the development of new drugs in each category, all the chapters have been revised to rewritten since the ninth edition two years ago.

The text is most useful for updating the practice of office-based family physicians because emphasis is placed on the rationale of therapeutic choices and because the drug categories cover the breadth of family practice. This is not a pharmacology review nor basic pharmacology text; in fact only one of the nearly 50 tables illustrates chemical structures, namely those of the phenothiazines. The majority of the tables summarize the dosage, indications, the contraindications for the selected drugs.

For the practitioner many benefits can be gained from this approach. For instance, because treatment of respiratory tract infections and hypertension comprises such a large proportion of family practice, a family physician should be delighted to read a discussion of the merits and drawbacks of the antitussive drugs (15 pages) and of the drugs for arterial hypertension (19 pages). Dermatological problems are discussed in 20 pages with therapies keyed to a dermatological formulary of 217 preparations.

One section of the book is out-of-date already, namely that dealing with arthritic drug therapy, because of the new antiarthritic oral agents recently made available. Still, this book is now more up-to-date than the second edition of the *AMA Drug Evaluations* and as such it deserves a place alongside every family physician's current medical therapy text and *Physicians' Desk Reference* for daily reference in practice.

Duane A. Lawrence, MD  
Virginia Beach, Virginia

**A Coursebook in Health Care Delivery.** Sidney Shindell, Jeffrey C. Salloway, and Colette M. Oberembt. Appleton-Century-Crofts, New York, 1976, 603 pp., \$22.50.

The material presented in this text is derived from a wide variety of sources. It encompasses epidemiology, public health, community medicine, legal medicine, and ethics. The first segment of the book reviews the major problems encountered by families throughout their lives. It notes the kinds of concerns and principal problems that individuals face from birth to old age. The second segment of the book analyzes the health-care system as it is presently structured.

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The text is readable and follows a logical sequence. Illustrated by tables, diagrams, and graphs, it provides a wealth of data on almost all of the major problems encountered by family physicians.

The social and community aspects of health-care delivery are presented clearly and lucidly. Family planning, venereal disease, health maintenance, risk appraisal, mental health, and degenerative disease all receive serious consideration. While one hesitates to attach undue importance to any one section, the chapter dealing with alcoholism and drug dependency has been exceptionally well done.

The present health-care delivery system is analyzed. The legislation dealing with public assistance and social insurance and the various payment mechanisms is presented in detail, including copies of the legislation. Existing health insurance programs are presented in an informative fashion.

The section on epidemiology and the epidemiological method is very readable. Illustrative cases have been used to demonstrate the investigation of both infectious diseases and vehicle-borne diseases as well as their method of solution.

In the final section, the legal aspects of medical practice are considered. The type of records that are required are outlined and stressed. The role of the physician in criminal law is well summarized. Details of wills and estates are thoroughly discussed. The differences in attitudes of the various religious persuasions and that impact on patient management and the effects upon the delivery of health care are presented. The ethical issues in medical practice are reviewed.

This is an excellent textbook for medical students and for students in the allied health professions. It also serves as a worthwhile reference and resource text for family practice residents and practicing physicians.

I. W. Bean, MD  
The Wellesley Hospital  
Toronto, Ontario

**Pain: A Personal Experience.** J. Blair Pace. Nelson-Hall Company, Chicago, 1976, 163 pp., \$7.95.

In *Pain: A Personal Experience*, Pace seems to have a double meaning for his title. He refers to his own work for many years as co-director of the Chronic Pain and Problem Back Service at Rancho Los Amigos Hospital, Downey, California, where a considerable staff of interested physicians has gathered for a team approach to these often complex problems; he also refers to the highly individual meaning of pain and to its conquests or relinquishment by the sufferer.

One of the group's techniques, often used after the traditional modalities have been exhausted, is "operant conditioning." This is based on a written contract in which the patient agrees to give up his disability step-by-step in exchange for positive "strokes" from the staff. The author claims it is highly effective.

Pace addresses his book to "injured laymen, insurance adjusters, and friends and families of injured people" rather than to physicians. The author explores some of the anatomy and physiology of pain, its ramifications and psychological overtones (particularly as chronic pain shades into depression), third parties, and the chronic-pain patient. Some of the other chapters are devoted to headache, trigger-point pain, bursitis and tendonitis, neuritis and neuralgia, slipped disc syndrome and whiplash, and spinal manipulation. I particularly enjoyed and learned a great deal from the chapter on acupuncture.

This easy volume will take the physician-reader scarcely an evening and perhaps will not reward his time; but paraprofessionals and those professionals sensitive to what their patients may be reading, and to what may be welcomed by their patients as suggested nontechnical reading, will find it of use.

Edward H. Kolner, MD  
Odana Medical Center  
Madison, Wisconsin

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## LOMOTIL®

brand of diphenoxylate hydrochloride with atropine sulfate

**IMPORTANT INFORMATION:** This is a Schedule V substance by Federal law; diphenoxylate HCl is chemically related to meperidine. In case of overdose or individual hypersensitivity, reactions similar to those after meperidine or morphine overdose may occur; treatment is similar to that for meperidine or morphine intoxication (prolonged and careful monitoring). Respiratory depression may recur in spite of an initial response to Narcan® (naloxone HCl) or may be evidenced as late as 30 hours after ingestion. LOMOTIL IS NOT AN INNOCUOUS DRUG AND DOSAGE RECOMMENDATIONS SHOULD BE STRICTLY ADHERED TO, ESPECIALLY IN CHILDREN. THIS MEDICATION SHOULD BE KEPT OUT OF REACH OF CHILDREN.

**Indications:** Lomotil is effective as adjunctive therapy in the management of diarrhea.

**Contraindications:** In children less than 2 years, due to the decreased safety margin in younger age groups, in patients who are jaundiced or hypersensitive to diphenoxylate HCl or atropine, and in diarrhea associated with pseudomembranous enterocolitis occurring during, or up to several weeks following, treatment with antibiotics such as clindamycin (Cleocin®) or lincomycin (Lincocin®).

**Warnings:** Use with special caution in young children, because of variable response, and with extreme caution in patients with cirrhosis and other advanced hepatic disease or abnormal liver function tests, because of possible hepatic coma. Diphenoxylate HCl may potentiate the action of barbiturates, tranquilizers and alcohol. In therapy, the concurrent use with monoamine oxidase inhibitors could precipitate hypertensive crisis. In severe dehydration or electrolyte imbalance, withhold Lomotil until corrective therapy has been initiated.

**Usage in pregnancy:** Weigh the potential benefits against possible risks before using during pregnancy, lactation or in women of childbearing age. Diphenoxylate HCl and atropine are secreted in the breast milk of nursing mothers.

**Precautions:** Addiction (dependency) to diphenoxylate HCl is theoretically possible at high dosage. Do not exceed recommended dosages. Administer with caution to patients receiving addicting drugs or known to be addiction prone or having a history of drug abuse. The subtherapeutic amount of atropine is added to discourage deliberate overdose; strictly observe contraindications, warnings and precautions for atropine; use with caution in children since signs of atropinism may occur even with the recommended dosage. Use with care in patients with acute ulcerative colitis and discontinue use if abdominal distention or other symptoms develop.

**Adverse reactions:** Atropine effects include dryness of skin and mucous membranes, flushing, hyperthermia, tachycardia and urinary retention. Other side effects with Lomotil include nausea, sedation, vomiting, swelling of the gums, abdominal discomfort, respiratory depression, numbness of the extremities, headache, dizziness, depression, malaise, drowsiness, coma, lethargy, anorexia, restlessness, euphoria, pruritus, angioneurotic edema, giant urticaria, paralytic ileus, and toxic megacolon.

**Dosage and administration:** Lomotil is contraindicated in children less than 2 years old. Use only Lomotil liquid for children 2 to 12 years old. For ages 2 to 5 years, 4 ml. (2 mg.) t.i.d.; 5 to 8 years, 4 ml. (2 mg.) q.i.d.; 8 to 12 years, 4 ml. (2 mg.) 5 times daily; adults, two tablets (5 mg.) t.i.d. to two tablets (5 mg.) q.i.d. or two regular teaspoonsfuls (10 ml., 5 mg.) q.i.d. Maintenance dosage may be as low as one fourth of the initial dosage. Make downward dosage adjustment as soon as initial symptoms are controlled.

**Overdosage:** Keep the medication out of the reach of children since accidental overdose may cause severe, even fatal, respiratory depression. Signs of overdose include flushing, hyperthermia, tachycardia, lethargy or coma, hypotonic reflexes, nystagmus, pinpoint pupils and respiratory depression which may occur 12 to 30 hours after overdose. Evacuate stomach by lavage, establish a patent airway and, when necessary, assist respiration mechanically. A narcotic antagonist may be used in severe respiratory depression. Observation should extend over at least 48 hours.

**Dosage forms:** Tablets, 2.5 mg. of diphenoxylate HCl with 0.025 mg. of atropine sulfate. Liquid, 2.5 mg. of diphenoxylate HCl and 0.025 mg. of atropine sulfate per 5 ml. A plastic dropper calibrated in increments of ½ ml. (total capacity, 2 ml.) accompanies each 2-oz. bottle of Lomotil liquid.

**SEARLE** Searle & Co.  
San Juan, Puerto Rico 00936

Address medical inquiries to:  
G. D. Searle & Co.  
Medical Communications Department  
Box 5110  
Chicago, Illinois 60680

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