

Norgesic[®] Forte

TABLETS

(orphenadrine citrate, 50 mg; aspirin,
770 mg; caffeine, 60 mg)

Stops the pain, not the patient.

Brief Summary

Indications:

1. Symptomatic relief of mild to moderate pain of acute musculo-skeletal disorders.
2. The orphenadrine component is indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute painful musculo-skeletal conditions.

The mode of action of orphenadrine has not been clearly identified, but may be related to its analgesic properties. Norgesic and Norgesic Forte do not directly relax tense skeletal muscles in man.

Contraindications:

Because of the mild anticholinergic effect of orphenadrine, Norgesic or Norgesic Forte should not be used in patients with glaucoma, pyloric or duodenal obstruction, achalasia, prostatic hypertrophy or obstructions at the bladder neck. Norgesic or Norgesic Forte is also contraindicated in patients with myasthenia gravis and in patients known to be sensitive to aspirin or caffeine.

The drug is contraindicated in patients who have demonstrated a previous hypersensitivity to the drug.

Warnings:

Norgesic Forte may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or driving a motor vehicle; ambulatory patients should therefore be cautioned accordingly.

Aspirin should be used with extreme caution in the presence of peptic ulcers and coagulation abnormalities.

Usage in Pregnancy:

Since safety of the use of this preparation in pregnancy, during lactation, or in the childbearing age has not been established, use of the drug in such patients requires that the potential benefits of the drug be weighed against its possible hazard to the mother and child.

Usage in Children:

The safe and effective use of this drug in children has not been established. Usage of this drug in children under 12 years of age is not recommended.

Precautions:

Confusion, anxiety and tremors have been reported in few patients receiving propoxyphene and orphenadrine concomitantly. As these symptoms may be simply due to an additive effect, reduction of dosage and/or discontinuation of one or both agents is recommended in such cases.

Safety of continuous long term therapy with Norgesic Forte has not been established; therefore, if Norgesic Forte is prescribed for prolonged use, periodic monitoring of blood, urine and liver function values is recommended.

Adverse Reactions:

Side effects of Norgesic or Norgesic Forte are those seen with aspirin and caffeine or those usually associated with mild anticholinergic agents. These may include tachycardia, palpitation, urinary hesitancy or retention, dry mouth, blurred vision, dilatation of the pupil, increased intraocular tension, weakness, nausea, vomiting, headache, dizziness, constipation, drowsiness and rarely, urticaria and other dermatoses. Infrequently an elderly patient may experience some degree of confusion. Mild central excitation and occasional hallucinations may be observed. These mild side effects can usually be eliminated by reduction in dosage. One case of aplastic anemia associated with the use of Norgesic has been reported. No causal relationship has been established. Rare G.I. hemorrhage due to aspirin content may be associated with the administration of Norgesic or Norgesic Forte. Some patients may experience transient episodes of light-headedness, dizziness or syncope.

Caution:

*Federal law prohibits dispensing without prescription. NG-7

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3K NF-1157

LETTERS TO THE EDITOR

ANTIHISTAMINE- DECONGESTANTS AND ACUTE OTITIS MEDIA

To the Editor:

I read the article by Schnore and colleagues, "Are Antihistamine-Decongestants of Value in the Treatment of Acute Otitis Media in Children?" (*Schnore SK, Sangster JF, Gerace TM, Bass MJ: J Fam Pract* 1986; 22:39-43), with considerable interest. It is a well-designed study but is far too small, with only 38 children in the treatment group and 44 in the placebo group.

With this in mind, the only thing proven is the old adage, "Beauty is in the eye of the beholder." I believe there is tantalizing evidence to support a conclusion that the medication may be of benefit, a conclusion diametrically opposed to the authors'.

The medicated group with a mean of 5.2 symptoms was significantly more ill than the control group with 4.2 symptoms ($P = .03$). This is supported by the fact that they utilized more of their medication (82 percent were compliant vs 63 percent) and required more acetaminophen (3.3 doses to 2.4).

Despite being more ill, the treated group improved more rapidly than the control group. This difference is most impressive at six days when extrapolated from the graph (Table 1).

Finally, it is of note that pneumatic otoscopy was abnormal in 12.1 percent of treated patients vs 24.4 percent of control at the conclusion of ther-

apy. Thus it appears to this reader that therapy that includes antihistamine-decongestant medication may also result in a lower incidence of post-treatment middle ear problems. As these differences are not statistically significant, it is my hope that a similar but much larger study will be undertaken to answer this question.

George H. Hess, MD
Carson Medical Group
Carson City, Nevada

PRIMARY CARE IN ACADEMIC HEALTH CENTERS

To the Editor:

Your recent article, "Whither Primary Care in the Academic Health Science Center?" (*Schwenk TL, Detmer DT: J Fam Pract* 1986; 23:489-493), was a stimulating review of the reasoning behind our institutional efforts in the development of primary care clinics both on our Academic Health Center campuses and in 25 remote locations. All of our clinics are corporately owned, and all of the physicians have faculty status. Over the last few years, this has led to increasing academic responsibility for the primary care physicians and has stimulated significant faculty development.

The family physician is the admitting and attending physician for all patients referred from the Ambulatory Care Network and the primary care clinics in the academic health centers. The family physician is responsible for health maintenance organization management and controls the nature and degree of specialty input. This clinic system will see approximately 250,000 patient visits this year, and will provide a learning laboratory for supervised student education for 100 junior and 100 senior medical students. Each student will spend 20 weeks, 8 in the junior year

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**TABLE 1. IMPROVEMENT SCORE
(Percentage Decrease in
Number of Symptoms)**

Day	Percent Antihistamine- Decongestant	Percent Placebo
5	68	60
6	78	65
10	83	80

ORNADE®

Each capsule contains 75 mg. phenylpropanolamine hydrochloride and 12 mg. chlorpheniramine maleate.

SPANSULE®

brand of sustained release capsules

For symptomatic relief of COLDS AND ALLERGIES

Before prescribing, see complete prescribing information in SK&F literature or PDR. The following is a brief summary.

Indications and Usage: For the treatment of the symptoms of seasonal and perennial allergic rhinitis and vasomotor rhinitis, including nasal obstruction (congestion); also for the treatment of runny nose, sneezing and nasal congestion associated with the common cold.

Contraindications: Hypersensitivity to either ingredient and chemically related antihistamines; severe hypertension; coronary artery disease; concurrent MAOI therapy. Newborns, premature infants, nursing mothers.

Warnings: May potentiate the effects of alcohol and other CNS depressants. Should not be taken simultaneously with other products containing phenylpropanolamine HCl or amphetamines.

Use with considerable caution in patients with narrow-angle glaucoma, stenosing peptic ulcer, pyloroduodenal obstruction, symptomatic prostatic hypertrophy, or bladder neck obstruction.

In infants and children, antihistamines in overdosage may cause hallucinations, convulsions, or death. They may also diminish mental alertness, and produce excitation, particularly in the young child.

In patients approx. 60 or older, risk of dizziness, sedation, and hypotension is greater.

Precautions: Use cautiously in patients with lower respiratory disease including asthma, hypertension, cardiovascular disease, hyperthyroidism, increased intraocular pressure, or diabetes.

Caution patients about activities requiring alertness (e.g., operating vehicles or machinery).

Drug interactions: MAOIs prolong and intensify the anticholinergic effects of antihistamines and potentiate the pressor effects of sympathomimetics.

Phenylpropanolamine HCl should not be used with ganglionic blocking drugs (e.g., mecamylamine) or with adrenergic blocking drugs (e.g., guanethidine sulfate or bethanidine).

Concomitant use of antihistamines may inhibit the action of oral anticoagulants; antagonize the action of β -adrenergic blockers; decrease the effects of corticosteroids; potentiate the cardiovascular effects of norepinephrine and the CNS depressant and atropine-like effects of anticholinergics. Concomitant use with phenothiazines may produce an additive CNS depressant effect; it may also cause urinary retention or glaucoma.

See also WARNINGS.

Carcinogenesis, mutagenesis, impairment of fertility: Chlorpheniramine Maleate—A long-term oncogenic study in rats produced no increase in the incidence of tumors in the drug-treated groups, as compared with controls, nor was evidence of mutagenicity found in a battery of mutagenic studies, including the Ames test. A reduction in fertility was observed in female rats at 67 times the human dose. Rabbits and rats, at doses up to 50 and 85 times the human dose, showed no reduction in fertility.

It is unknown whether phenylpropanolamine HCl has carcinogenic or mutagenic effects or impairs fertility.

Pregnancy, teratogenic effects, pregnancy category B: Reproduction studies with chlorpheniramine maleate in rabbits and rats at doses up to 50 and 85 times the human dose and with phenylpropanolamine HCl in rats at doses up to 7 times the human dose revealed no harm to the fetus. There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, 'Ornade' should be used during pregnancy only if clearly needed.

Nonteratogenic Effects: Studies of chlorpheniramine maleate in rats showed a decrease in the postnatal survival rate of offspring of animals dosed with 33 and 67 times the human dose.

Nursing Mothers: See CONTRAINDICATIONS.

Pediatric use: Safety and effectiveness in children under 12 years have not been established.

Adverse Reactions: The following have been reported with antihistamines and/or sympathomimetic amines: anaphylactic shock; chills; drug rash; excessive dryness of mouth, nose and throat; increased intraocular pressure; excessive perspiration; photosensitivity; urticaria; weakness; angina pain; extrasystoles; headache; hypertension; hypotension; palpitations; tachycardia; agranulocytosis; hemolytic anemia; leukopenia; thrombocytopenia; blurred vision; confusion; convulsions; diplopia; disturbed coordination; dizziness; drowsiness; euphoria; excitation; fatigue; hysteria; insomnia; irritability; acute labyrinthitis; nervousness; neuritis; paresthesia; restlessness; sedation; tinnitus; tremor; vertigo; abdominal pain; anorexia; constipation; diarrhea; epigastric distress; nausea; vomiting; dysuria; early menses; urinary frequency; urinary retention; thickening of bronchial secretions; tightness of chest and wheezing; nasal stuffiness.

How Supplied: Bottles of 50 and 500 capsules; in Single Unit Packages of 100 capsules (intended for institutional use only).

BRS-OR-L35

Smith Kline & French Laboratories

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and 12 in the senior year, in this setting. We have experienced the benefits outlined in the Schwenk and Detmer essay. Additionally, the program has allowed us to build faculty, as a majority of our family medicine residency graduates have made a career choice to remain with, practice in, and teach in our clinic system.

Frederic N. Schwartz, DO
Chairman, Department of Family
Medicine
Chicago College of Osteopathic
Medicine
Vice-President, Ambulatory Care
Network
Chicago Osteopathic Ambulatory
Care Facilities Corporation
Chicago Osteopathic Health
Systems

PSYCHOSOCIAL SCREENING MEASURES

To the Editor:

The study by Hilliard et al (*Hilliard R, Gjerde C, Parker L: Validity of two psychological screening measures in family practice: Personal inventory and family APGAR. J Fam Pract 1986; 23:345-349*) does not address the first question I have always heard asked by residents and students when discussing behavioral screening measures, "Why bother?" The authors describe the instruments as "screening" tests, yet they measure the validity by residents' detection of "symptoms." If the usual history taking and physical examination detects symptoms as well as or better than the "screening" test, then the test is unnecessary. The crucial group of "false-positive" patients was not further investigated. I wish they had been. Only if screening tests detect significant health problems missed by physicians' customary habits will physicians be likely to change practice styles. Otherwise, these measures may have research utility but probably will

not be incorporated into clinical practice.

David M. Baughan, MD
Assistant Clinical Professor
Division of Community and Family
Medicine
University of California, San Diego
School of Medicine

CHOICE OF INSTRUMENT FOR FLEXIBLE SIGMOIDOSCOPY

To the Editor:

In his article Dr. Dervin¹ concludes that the 105-cm flexible sigmoidoscope may be an appropriate screening instrument for family physicians and should be evaluated as such. This proposal stands in contrast to a rather large body of research that suggests that the shorter, 35-cm flexible sigmoidoscope is the most reasonable instrument for use by generalists in screening asymptomatic, average-risk patients.

Although longer instruments can obviously increase sensitivity, or diagnostic yield, if they are inserted farther, it is not clear that the increase is proportional to the added length of insertion.² In several studies reporting the anatomic distribution of lesions detected with the 60- or 65-cm sigmoidoscope,³⁻⁵ a much higher proportion of all lesions were found in the area from 20 to 35 cm than in the area from 36 to 60 cm. The 105-cm instrument will routinely accomplish examination of the descending colon when fully inserted, while 65-cm sigmoidoscopes, on average, reach the junction of the sigmoid and descending colon.⁶ The descending colon yields a very small proportion of all colorectal cancers according to SEER data.⁷ Thus the added depth of insertion may not be as beneficial as expected. Moreover, even in Dervin's experienced hands, insertion beyond 65 cm was accomplished in only 57 percent of cases. In the less-experi-

enced hands of the average family physician or internist, this proportion is apt to be much lower.

The choice of a screening test requires consideration of other factors in addition to diagnostic yield. Several reports have noted that the use of the 35-cm sigmoidoscope is much more readily mastered and subsequently used than the 65-cm instrument.^{2,8}

Patient discomfort has uniformly been shown to be less with the 35-cm sigmoidoscope than with either the 65-cm sigmoidoscope or the 25-cm rigid instrument.^{3-5,9} Examination with the 35-cm flexible sigmoidoscope and the rigid instrument requires about the same amount of time, while examination with the 65-cm sigmoidoscope requires twice the time.^{3-5,9} These factors will all influence the effectiveness of efforts to increase patient and clinician acceptance of screening sigmoidoscopy. If a large-scale trial of screening sigmoidoscopy is indicated, and I believe that it is, the evidence supports evaluation of the 35-cm flexible sigmoidoscope rather than longer instruments.

Joe V. Selby, MD, MPH
Division of Research
The Permanente Medical Group
Oakland, California

References

1. Dervin JV: Feasibility of 105-cm flexible sigmoidoscopy in family practice. *J Fam Pract* 1986; 23:341-344
2. Shapiro M, Aslander MO, Getzug SJ, et al: Flexible fiberoptic training of non-endoscopic physicians in the community hospital, abstract. *Gastrointest Endosc* 1983; 29:186
3. Bohlman TW, Katon RM, Lipshutz GR, et al: Fiberoptic pansigmoidoscopy: An evaluation and comparison with rigid sigmoidoscopy. *Gastroenterology* 1977; 72:644-649
4. Dubow RA, Katon RM, Benner KG, et al: Short (35-cm) versus long (60-cm) flexible sigmoidoscopy: A comparison of findings and tolerance in asymptomatic patients screened for colorectal neoplasia. *Gastrointest Endosc* 1985; 31:305-308
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8. Winawer SJ, Cummins R, Baldwin MP, et al: A new flexible sigmoidoscope for the generalist. *Gastrointest Endosc* 1982; 28:233-236
9. Grobe JL, Kozarek RA, Sanowski RA: Flexible versus rigid sigmoidoscopy: A comparison using an inexpensive 35-cm flexible proctosigmoidoscope. *Am J Gastroenterol* 1983; 78:569-571

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

I would like to respond to the letter submitted by Dr. Selby, who raises several important issues. The ability of 105-cm flexible sigmoidoscopy to screen the descending colon is not an issue. The writer states, however, that the descending colon yields a small percentage of cancers. Shinya's data indicate that 23 percent of polyps are located in this region.¹

Another question is whether insertion beyond 65 cm 57 percent of the time is an important advantage. It may well be if a significant yield of additional polyps can be demonstrated in future studies. Along with this issue is raised the point that not all family physicians will achieve these results. Skilled technique is a traditional challenge to most technical advancements in family practice. If 105-cm flexible sigmoidoscopy were to become the standard in family practice, I am confident that this skill could be taught to our students and colleagues.

Finally, the writer argues that the 35-cm sigmoidoscope is superior to the 60-cm sigmoidoscope for screening in terms of ease of learning, patient discomfort, and time of examination. The 60-cm instrument is clearly accepted as the standard for family practice. Arguments for the 35-cm examination have not convinced family physicians.

John V. Dervin, MD
Santa Rosa, California

Reference

1. Shinya H, Cooperman A, Wolff WI: A rationale for the endoscopic management of colonic polyps. *Surg Clin North Am* 1982; 62:861-867

NEEDLE ASPIRATION AND CELLULITIS

To the Editor:

I would like to commend *The Journal* for publishing Dr. Ted Epperly's research on the value of needle aspiration (*Epperly TD: The value of needle aspiration in the management of cellulitis. J Fam Pract* 1986; 23:337-340). Dr. Epperly's work is an example of the kind of research that family physicians can and should do: research that helps to answer common, practical, but important questions. I feel more secure in my practice of treating cellulitis empirically without performing needle aspiration, even though I was taught to do needle aspiration as a medical student.

Dr. Epperly concludes correctly that different sites of aspiration have similar yields, and that no significant differences in ancillary tests and signs (white cell count and differential, erythrocyte sedimentation rate, and temperature) exist between aspirate-positive and aspirate-negative patients. These findings, along with the low yield of the aspirations and the finding of common pathogens in positive aspirates, buttress Dr. Epperly's conclusion that needle aspiration is of no significant benefit in his population. To truly determine the value of needle aspiration in cellulitis, however, information on patient outcome is necessary. For example, if a patient's aspirate grew *Staphylococcus aureus* resistant to erythromycin and the patient had been empirically started on erythromycin, it is possible that the positive aspirate would shorten the patient's course by alerting his physician to change the patient's treatment before the need for such a change became obvious clinically.

To answer the question definitively, a study that randomized patients to aspiration and no-aspiration

groups and then compared outcomes would be necessary. Although I feel it is unlikely that significant differences in outcome would be found, such a study would provide even better evidence of the value of needle aspiration in cellulitis.

James P. Richardson, MD
Department of Family Medicine
University of Maryland School of
Medicine
Baltimore

To the Editor:

As family physicians in rural northern New York, we read with interest the study by Dr. Epperly documenting the relatively low yield of positive cultures from needle aspiration in cellulitis (Epperly TD: *The value of needle aspiration in the management of cellulitis. J Fam Pract* 1986; 23:337-340).

A potentially useful observation we made from the study was not commented on in the report. The edge and midpoint were each positive about one twelfth of the time and were positive independently of each other. Consequently, in this study doing two aspirations on a lesion doubled the yield, and it is likely that doing further aspirations would further increase the yield. It would, therefore, seem to be logical to do multiple aspirations in a case where it is important to recover the causative bacteria. Perhaps the aspirates could be pooled into a single culture specimen so that the cost increase for this increased yield could be kept minimal.

Cost vs benefit certainly is a central issue in deciding how far to pursue a bacterial identification in a case of cellulitis. It would be interesting to know how many of the positive cultures turned out to be useful in the

management of the cellulitis and also how many of the 103 total cases failed to resolve on empirical antibiotic therapy. The findings would identify the group who did or would have benefited sufficiently from the isolation of the etiologic agent to justify the expense and discomfort to the patient of obtaining the aspiration.

Jay W. Chapman, MD
Patricia Ledden Chapman, MD
North Oswego County Health
Services
Pulaski, New York

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

The observations noted by Drs. Chapman and Chapman are good ones. Indeed, pooled aspirations from multiple sites would increase yield. However, from the data obtained from the population in this study, the organisms recovered proved to be what one would empirically predict (ie, staphylococcus and streptococcus species). Therefore, multiple painful aspirations would only increase the chance of recovering organisms that would be suspected clinically and would not be warranted in this young healthy population. If the patient were immunocompromised, elderly, or not responding to therapy, however, it may be worthwhile to do multiple aspirations to increase the yield of possible unsuspected organisms.

All of the patients in this study responded to either oral or intravenous antibiotics aimed empirically at staphylococcus and streptococcus organisms, and the positive wound or aspirate cultures did not alter management.

Ted D. Epperly, MD
Medical Corps
Fort Benning, Georgia

ANOREXIA IN APPENDICITIS

To the Editor:

Allow me to comment on the excellent article regarding abdominal pain in pregnancy by Ellsbury (Ellsbury KE: *Abdominal pain in pregnancy. J Fam Pract* 1986; 22:365-371). Under the symptoms associated with appendicitis, it lists anorexia in 5 percent.

Generally, many would consider this to be the one of the significant features of appendicitis. Perhaps there has been a misprint, as this symptom should occur in a significant percentage of appendicitis patients.

William V. Dolan, OFM, MD
Surgery Service
Alaska Native Medical Center
Ankorage, Alaska

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

Dr. Dolan has correctly identified a typographical error. The actual figure in Table 1 under "Appendicitis" should read anorexia in 50 percent, not 5 percent. This figure represents an average for ten reported series, where the prevalence of anorexia in appendicitis patients ranges from 25 percent in Mohammed's series¹ to 100 percent in Zaitoon's series.²

Kathleen E. Ellsbury, MD
Department of Family Medicine
University of Washington
Seattle, Washington

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