

# 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 overdosage or individual hypersensitivity, reactions similar to those after meperidine or morphine overdosage 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, and in patients who are jaundiced or hypersensitive to diphenoxylate HCl or atropine.

**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 overdosage; 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 teaspoonfuls (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 overdosage may cause severe, even fatal, respiratory depression. Signs of overdosage 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.

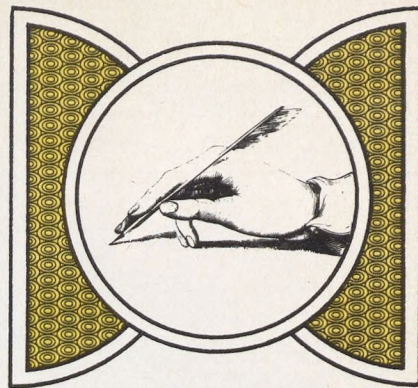
**Dosage forms:** Tablets, 2.5 mg. of diphenoxylate HCl with 0.025 mg. of atropine sulfate. Liquid, 2.5 mg. of diphenoxylate HCl and 0.025 mg. of atropine sulfate per 5 ml. A plastic dropper calibrated in increments of ½ ml. (total capacity, 2 ml.) accompanies each 2-oz. bottle of Lomotil liquid.

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

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

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## 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.

### On Obstetrics in Family Practice

To the Editor:

The recent article by Mehl et al in *The Journal* (Mehl LE, Bruce C, Renner J; *Importance of obstetrics in a comprehensive family practice. J Fam Pract* 3:385-389, 1976) causes me some concern. It is the thesis of the authors that family practice groups practicing without obstetrics not only do very little obstetrics, but consequently, little pediatrics, gynecology, and family therapy.

I agree with the introduction regarding the need for the family physician to be occupied with the entire family without regard to issues of age or sex. The problems arise with the methodology and numbers used to support the authors' conclusions.

It is stated that all four practices studied were composed of members who entered practice with plans to deliver comprehensive, continuous family health care. The authors mention that members of each of the four practices included individuals with one or two years of post-medical school training, but we are not told about the details of that training with respect to whether the physicians were primarily educated through a rotating internship background or within a recognized and certified family practice program. This is the basic flaw in the paper since, on

the basis of the results, we are supposed to think carefully about the future of obstetrics in family practice training programs. This we cannot really do, since we have no basis for comparison.

The results of the study show that out of four family practices, the two which did obstetrics also did a reasonable amount of pediatrics, gynecology, and family therapy. The two that did little or no obstetrics were also inactive in the other areas.

The authors then attempted to relate the actual practice to attitudes of the practitioners including satisfaction with their current style and plans for potential change. This area of their study can be summarized by saying that those who were doing obstetrics and the other related disciplines were happy and planned to continue doing what they were doing, while those practitioners who did not were unhappy, insecure in the other areas, and furthermore, were considering changing fields from family practice into other, more narrow fields, such as emergency medicine, or perhaps going for additional training in one of the traditional specialties. My interpretation of their Table 1 on attitudes relates simply to the observation that

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# Iberet<sup>®</sup>-500

One Filmtab<sup>®</sup> tablet a day supplies:

## Controlled-Release Iron

Ferrous Sulfate,  
(equivalent to  
elemental iron—105 mg.) . . . 525 mg.

## Plus High Potency Vitamin C

Vitamin C  
(as Sodium Ascorbate) . . . . . 500 mg.

## Plus the B-Complex

(contains no folic acid)

Niacinamide . . . . . 30 mg.

Calcium Pantothenate . . . . . 10 mg.

Vitamin B<sub>1</sub>  
(Thiamine Mononitrate) . . . . . 6 mg.

Vitamin B<sub>2</sub> (Riboflavin) . . . . . 6 mg.

Vitamin B<sub>6</sub>  
(Pyridoxine Hydrochloride) . . . 5 mg.

Vitamin B<sub>12</sub>  
(Cyanocobalamin) . . . . . 25 mcg.

INDICATIONS: For conditions in which iron deficiency occurs concomitantly with deficient intake or increased need for the B-complex vitamins (contains no folic acid).

# Iberet-Folic-500<sup>®</sup> Rx

One Filmtab tablet a day supplies the same formula as Iberet-500 plus:

**Folic Acid . . . . . 800 mcg.**

INDICATIONS: In non-pregnant adults, for the treatment of iron deficiency and prevention of concomitant folic acid deficiency where there is an associated deficient intake or increased need for the B-complex vitamins. Also indicated in pregnancy for the prevention and treatment of iron deficiency where there is a concomitant deficient intake or increased need for B-complex vitamins (including folic acid).

CONTRAINDICATION: Pernicious anemia.

WARNINGS: Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B<sub>12</sub> is deficient.

PRECAUTION: Where anemia exists, its nature should be established and underlying causes determined. Iberet-Folic-500 contains 800 mcg. of folic acid per tablet. Folic acid especially in doses above 1.0 mg. daily may obscure pernicious anemia, in that hematologic remission may occur while neurologic manifestations remain progressive.

ADVERSE REACTIONS: The likelihood of gastric intolerance is remote. If such should occur, the tablet may be taken after a meal. Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

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Gradumet<sup>®</sup>—Controlled-release dose form, Abbott.  
Filmtab—Film-sealed tablets, Abbott.



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those who were secure in their full role of family physicians were happy, while those who were not secure were unhappy. Without basic information on training, however, my interpretation is possibly unfounded.

On page 387, the statistical significance between the groups based on the characteristics of their patient distribution is given with p values in almost all cases less than 0.001. In my opinion, this presentation represents a misuse of statistics. The fact is that the number of cases is small and the dependent versus the independent variables are connected in a non-causal way. As mentioned earlier, if the groups are basically non-comparable because their backgrounds differ substantially, the fact that there is a coincidental statistical significance neither adds support to, nor detracts from, the generalizations being made.

Similarly, the elaborate graphic and tabular presentation of the basic facts, which show the described differences in practice and attitude, appear to me to go beyond the solidity of the data, especially since we again are missing some key information upon which interpretation might become reasonable.

The San Francisco Bay area community is over-doctored and heavily oriented towards the traditional specialties. The community standard is to have a pediatrician, or an internist, or an obstetrician/gynecologist. Therefore, the family practitioner who elects to practice family medicine in its fully comprehensive form must be attitudinally and cognitively prepared to compete in that buyer's marketplace. If he is to practice obstetrics, pediatrics, family therapy, etc, he must be extremely well trained and sure in his role, since he is going against the community standard. It is, therefore, unreasonable to expect that the possibly inadequately trained family physicians who composed at least practices 3 and 4, could effectively compete in that environment. Those who made up practices 3 and 4 at the outset, or over time, appeared to degenerate into some variety of generalist for adults, and we do not

even know how they were trained for that role.

Finally, the authors suggest that for the concept of comprehensive family medicine to remain viable, obstetrics must remain an important part of family practice. This certainly cannot be denied. They suggest further, presumably on the basis of their data, that residents not planning to include obstetrics in their future practice might best join a primary care, internal medicine program.

This conclusion is perhaps their opinion, but cannot be based on the data that they present for the reasons already described. It is an oversimplified suggestion, perhaps based on the authors' own feelings about what a family practice ought to be. It neglects the possibility that there are multiple possible variations within a family medicine context depending on the environment, and the orientation of the graduate of the program.

For example, it may be just possible that family practitioners in the San Francisco Bay area, and in other similar, urban environments, may have some difficulty in building up a substantial obstetrical practice because of the community standard and ob/gyn physician over-supply (a fact not supported by the figures for practices 1 and 2). The family physician wishing to do more obstetrics and gynecology because he wants to and has been trained to, may find the alternative model of close association with a sympathetic and supportive ob/gyn group to allow excellent family-oriented obstetrical care, delivered in a family medicine context, while still preserving optimal care for his patients both at the human and technical level.

I suggest this only as one possible alternative to dumping those who do not fit within a particular mold to the as-yet-undefined and untested role of the primary care internist.

In summary, I found the article to be interesting and extremely thought-provoking, but disturbing in a journal that has been preeminent in helping to develop a scientific base for the discipline of family medicine.

Michael Klein, MD  
Director, Department of  
Family Medicine  
McGill University  
Montreal, Quebec