

Gantanol[®] DS

sulfamethoxazole/Roche

Double Strength Tablets

Before prescribing, please consult complete product information, a summary of which follows:

Indications: Acute, recurrent or chronic urinary tract infections (primarily pyelonephritis, pyelitis and cystitis) due to susceptible organisms (usually *E. coli*, *Klebsiella-Aerobacter*, staphylococcus, *Proteus mirabilis* and, less frequently, *Proteus vulgaris*), in the absence of obstructive uropathy or foreign bodies. Note: Carefully coordinate *in vitro* sulfonamide sensitivity tests with bacteriologic and clinical response; add aminobenzoic acid to follow-up culture media. The increasing frequency of resistant organisms limits the usefulness of antibacterials including sulfonamides, especially in chronic or recurrent urinary tract infections. Measure sulfonamide blood levels as variations may occur; 20 mg/100 ml should be maximum total level.

Contraindications: Sulfonamide hypersensitivity; pregnancy at term and during nursing period; infants less than two months of age.

Warnings: Safety during pregnancy has not been established. Sulfonamides should not be used for group A beta-hemolytic streptococcal infections and will not eradicate or prevent sequelae (rheumatic fever, glomerulonephritis) of such infections. Deaths from hypersensitivity reactions, agranulocytosis, aplastic anemia and other blood dyscrasias have been reported and early clinical signs (sore throat, fever, pallor, purpura or jaundice) may indicate serious blood disorders. Frequent CBC and urinalysis with microscopic examination are recommended during sulfonamide therapy. Insufficient data on children under six with chronic renal disease.

Precautions: Use cautiously in patients with impaired renal or hepatic function, severe allergy, bronchial asthma; in glucose-6-phosphate dehydrogenase-deficient individuals in whom dose-related hemolysis may occur. Maintain adequate fluid intake to prevent crystalluria and stone formation.

Adverse Reactions: *Blood dyscrasias* (agranulocytosis, aplastic anemia, thrombocytopenia, leukopenia, hemolytic anemia, purpura, hypoprothrombinemia and methemoglobinemia); *allergic reactions* (erythema multiforme, skin eruptions, epidermal necrolysis, urticaria, serum sickness, pruritus, exfoliative dermatitis, anaphylactoid reactions, periorbital edema, conjunctival and scleral injection, photosensitization, arthralgia and allergic myocarditis); *gastrointestinal reactions* (nausea, emesis, abdominal pains, hepatitis, diarrhea, anorexia, pancreatitis and stomatitis); *CNS reactions* (headache, peripheral neuritis, mental depression, convulsions, ataxia, hallucinations, tinnitus, vertigo and insomnia); *miscellaneous reactions* (drug fever, chills, toxic nephrosis with oliguria and anuria, periarthritis nodosa and L.E. phenomenon). Due to certain chemical similarities with some goitrogens, diuretics (acetazolamide, thiazides) and oral hypoglycemic agents, sulfonamides have caused rare instances of goiter production, diuresis and hypoglycemia as well as thyroid malignancies in rats following long-term administration. Cross-sensitivity with these agents may exist.

Dosage: Systemic sulfonamides are contraindicated in infants under 2 months of age (except adjunctively with pyrimethamine in congenital toxoplasmosis). Usual adult dosage: 2 Gm (2 DS tabs or 4 tabs or 4 teasp.) initially, then 1 Gm b.i.d. or t.i.d. depending on severity of infection.

Usual child's dosage: 0.5 Gm (1 tab or teasp.) /20 lbs of body weight initially, than 0.25 Gm/20 lbs b.i.d. Maximum dose should not exceed 75 mg/kg/24 hrs.

Supplied: DS (double strength) Tablets, 1 Gm sulfamethoxazole; Tablets, 0.5 Gm sulfamethoxazole; Suspension, 0.5 Gm sulfamethoxazole/teaspoonful.

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.



Treatment of Near-Drowning To the Editor:

Regarding the "Self-Assessment in Family Practice" article on near-drowning (*J Fam Pract* 5:877, 1977), nasogastric decompression of the stomach should be included as one of the high priority procedures to be performed in a near-drowning situation.

There are three reasons nasogastric decompression is indicated:

1. To prevent mechanical interference with ventilation caused by large volumes of swallowed water¹
2. To decrease the possibility of aspiration of gastric contents²
3. To prevent the gastrointestinal absorption of water which might result in dilutional hyponatremia.³

David B. Sills
Fourth year medical student
Office of Student Affairs
Baylor College of Medicine
Houston, Texas

References

1. Graves SA: Drowning and near-drowning. In Vaughan VC III, McKay RJ, Nelson WE (eds): *Nelson Textbook of Pediatrics*, ed 10. Philadelphia, WB Saunders, 1975, p 278

2. Gilfoil MP, Carvajal HF: Near-drowning in children. *Tex Med* 73:773, 1977

3. Kohaut E: Near-drowning. Presented at Baylor College of Medicine Pediatric Grand Rounds, Texas Children's Hospital, Houston, Texas, May 2, 1976

Value of Routine Screening Procedures

To the Editor:

I have two comments about the article, Screening During Routine Health Assessment, by Kirkwood and Fromm (*J Fam Pract* 5:510, 1977). The first comment concerns their methods, the second concerns their philosophy.

Their Methods: Inclusion in the study of several items involving judgment makes the results difficult or impossible to interpret. This includes not just items like "social history" but, strangely enough, even the numerical data of certain laboratory tests. I could go through their Table I ("Definition of Abnormality. . .") item by item to demonstrate this, but I will just choose one point from each of the Procedure categories in that table.

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Roche Laboratories
Division of Hoffmann-La Roche Inc.
Nutley, New Jersey 07110

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a. **Physical Examination:** A particular heart murmur could be recorded as "functional systolic ejection murmur" or "grade 1/6 systolic ejection murmur." They would both be recorded as abnormalities, but one would be recorded as having been followed up, and the other not. Similarly, how would the authors have handled the recording of a "moderately" enlarged prostate in an asymptomatic 65-year-old man when there was no further comment in the chart?

b. **Social History:** An abnormality here is defined as the "presence of a situation amenable to intervention." In whose opinion? There is enormous variation between professionals as to whether intervention is practical or helpful in different situations.

c. **Chemical Blood Screen:** An abnormality is "a result deviating from a laboratory-established normal range." Physicians in practice know that the laboratory-established (statistically-derived) normal range is not always the "homeostatic" normal range nor the "actuarial" normal range. They may for very good reasons choose to consider that a result which is slightly outside the laboratory-established range is in fact normal. In that quite common case they are very unlikely to ask a secretary to spend time retrieving a chart, and spend their own time making a notation about a situation that they do not consider pathological anyway.

The above problems make it impossible for me to interpret the results of the whole study regarding the number of abnormalities and follow-up.

Philosophy: More important than the above, however, is the signifi-

cance that abnormalities should be sought, and if found, should lead to some action. All this without proof that most of this costly and sometimes dangerous business helps the patient. Of course I am referring to the Process vs Outcome argument. The authors indicate at the beginning of the article that they are very well aware of this problem and mention those very few items of screening that may indeed be helpful (if the patient complies with treatment—another unknown). They also state the full impact of what I am trying to say when they conclude at the very end of the article: "It is difficult to escape the moral and perhaps legal implications for health-care providers to at least react to an abnormal finding. Response to this imperative may be facilitated by performance of only those screening procedures whose practical value in affecting ultimate outcome has been fully demonstrated." To my mind, then, the very beginning and the very end don't jibe with the main body of the article.

The only conclusions which can be drawn from this study are:

a. for the researcher, don't try to pick out "normal" and "abnormal" retrospectively from patient records, even with an exemplary charting system, and

b. for the clinician, don't do any screening procedures until a beneficial outcome shall have been proved for that procedure.

*Stanley Sinclair, MD
Director of Education
Herzl Family Practice Center
Assistant Professor of Family
Medicine, McGill University
Montreal, Quebec*

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Ascodeen-30®

Each tablet contains: codeine phosphate, 30 mg (gr 1/2), (Warning—may be habit-forming); and aspirin, 325 mg.

- additive potency of aspirin and codeine
- anti-inflammatory/analgesic
- effective relief of moderate pain

CONTRAINDICATIONS: Hypersensitivity to aspirin or codeine.

WARNINGS: Drug dependence: Codeine can produce drug dependence of the morphine type and, therefore, has the potential for being abused. Psychic dependence, physical dependence and tolerance may develop upon repeated administration of this drug and it should be prescribed and administered with the same degree of caution appropriate to the use of other oral, narcotic-containing medications. Like other narcotic-containing medications, the drug is subject to the Federal Controlled Substances Act.

Use in ambulatory patients: These products may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery. The patient using these drugs should be cautioned accordingly.

Interaction with other central nervous system depressants: Patients receiving other narcotic analgesics, general anesthetics, phenothiazines, other tranquilizers, sedative-hypnotics, or other CNS depressants (including alcohol) concomitantly with these products may exhibit an additive CNS depression. When such combined therapy is contemplated, the dose of one or both agents should be reduced.

Use in pregnancy: Safe use in pregnancy has not been established relative to possible adverse effects on fetal development. Therefore, these products should not be used in pregnant women unless, in the judgment of the physician, the potential benefits outweigh the possible hazards.

PRECAUTIONS: Allergic: Precautions should be taken in administering salicylates to persons with known allergies; patients with nasal polyps are especially likely to be hypersensitive to the medication. Salicylates should be used with caution in patients with active peptic ulcers.

Head injury and increased intracranial pressure: The respiratory depressant effects of narcotics and their capacity to elevate cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury, other intracranial lesions or a pre-existing increase in intracranial pressure. Furthermore, narcotics produce adverse reactions which may obscure the clinical course of patients with head injuries.

Acute abdominal conditions: The administration of these products or other narcotics may obscure the diagnosis or clinical course in patients with acute abdominal conditions.

Special risk patients: These products should be given with caution to certain patients such as the elderly or debilitated, and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, and prostatic hypertrophy or urethral stricture.

ADVERSE REACTIONS: Some patients are unable to take salicylates without developing nausea and vomiting. Hypersensitivity may be manifested by a skin rash or even an anaphylactic reaction. With these exceptions, most of the side effects occur after repeated administration of large doses. They include headache, vertigo, ringing in the ears, mental confusion, drowsiness, sweating, thirst, nausea, and vomiting. Occasional patients experience gastric irritation and bleeding with aspirin. The most frequently observed adverse reactions include lightheadedness, dizziness, sedation, nausea and vomiting. These effects seem to be more prominent in ambulatory than in nonambulatory patients, and some of these adverse reactions may be alleviated if the patient lies down. Other adverse reactions include euphoria, dysphoria, constipation and pruritus.

DRUG INTERACTIONS: The CNS depressant effects of these products may be additive with that of other CNS depressants.

HOW SUPPLIED: Bottles of 100, 1000, and Dispenserpak® of 25.



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Research Triangle Park
North Carolina 27709

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The preceding letter was referred to Drs. Kirkwood and Froom who respond as follows:

We very much appreciated Dr. Sinclair's observations and criticisms of our study and will attempt to respond. To do so we would like to paraphrase his comments into the following:

1. *The significance of results and follow-up is difficult to interpret due to definitions of "abnormality" which involve judgment.*

To reply to specific objections, first, as was noted, all physical findings were scored by the physician as "abnormal or normal." Thus, we accepted his judgment and did not impose ours. Secondly, although many physicians do, in fact, ignore laboratory designations of "abnormal," we question this practice on the grounds that if the results were to prove clinically significant, there would be no recorded clinical context to justify the omission. Finally, we can only agree that the evaluation of social and family histories is difficult. We did not include them in order to make a definitive statement about results and follow-up, but rather, since they are often included in periodic "physical examination" protocols, they were included merely to report data which we had not seen reported previously.

We strongly disagree with Dr. Sinclair's statement that all conclusions about abnormalities or follow-up from this study are unwarranted. Surely the results of

blood pressure readings, stool guaiacs, vaginal cytologies, hemato-crits, ECGs, chest x-rays, etc, are as unambiguous as any in medicine. Furthermore, several of these (blood pressure, pap smear, stool for occult blood) are accepted as being of value using the strict criterion for efficacy that we noted. In spite of that, follow-up was not significantly improved for these latter tests over those which indeed may have been ignored consciously by the physician group we studied.

2. *The main body of the paper, as reported, stands as an endorsement of seeking abnormalities and taking action.*

We regret that Dr. Sinclair reached this conclusion. We felt that from the inception of this study that, although "yearly physicals" are a hoary ritual in primary care, the results from such activities had previously been unreported in the literature. Thus, we reported the results of one such program in its entirety; if you will, warts and all. Also, because reviews published in this *Journal* and *Lancet* had more sharply defined those problems for which screening is probably of value, we were additionally interested in those specific procedures, especially within the context of a family practice.

C. Richard Kirkwood, MD
Anacortes, Washington

Jack Froom, MD
Associate Professor of Family
Medicine and
Director of Research
Family Medicine Program
University of Rochester-Highland
Hospital
Rochester, New York

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 3 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 theory, 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, but 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 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 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 1/2 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