

## Aldactazide®

(spironolactone 50 mg/hydrochlorothiazide 50 mg)

### WARNING:

Spironolactone, an ingredient of Aldactazide, has been shown to be a tumorigen in chronic toxicity studies in rats (see *Warnings*). Aldactazide should be used only in those conditions described in the *Indications* section of the complete prescribing information. Unnecessary use of this drug should be avoided. Fixed-dose combination drugs are not indicated for initial therapy of edema or hypertension. Edema or hypertension requires therapy titrated to the individual patient. If the fixed combination represents the dosage so determined, its use may be more convenient in patient management. The treatment of hypertension and edema is not static, but must be reevaluated as conditions in each patient warrant.

**Contraindications:** Anuria, acute renal insufficiency, significant impairment of renal function, hyperkalemia or acute or severe hepatic failure. Allergy to thiazide diuretics or to other sulfonamide-derived drugs.

**Warnings:** Excessive potassium intake may cause hyperkalemia. Potassium supplements should not be given with Aldactazide. Do not administer concurrently with other potassium-sparing diuretics. Sulfonamide derivatives including thiazides have been reported to exacerbate or activate systemic lupus erythematosus. Spironolactone has been shown to be a tumorigen in chronic toxicity studies in rats. In one study using 25, 75 and 250 times the usual daily human dose (2 mg/kg) there was a statistically significant dose-related increase in benign adenomas of the thyroid and testes. In female rats there was a statistically significant increase in malignant mammary tumors at the mid-dose only. In male rats there was a dose-related increase in proliferative changes in the liver. At the highest dosage level (500 mg/kg) the range of effects included hepatocytomegaly, hyperplastic nodules and hepatocellular carcinoma; the last was not statistically significant.

**Precautions:** Patients should be carefully evaluated for possible disturbances of fluid and electrolyte balance. Hyperkalemia may occur in patients with impaired renal function or excessive potassium intake and can cause cardiac irregularities which may be fatal. Hypokalemia may develop as a result of profound diuresis, particularly when Aldactazide is used concomitantly with loop diuretics, glucocorticoids or ACTH. Transient elevation of BUN may occur. Reversible hyperchloremic metabolic acidosis may occur in some patients with decompensated hepatic cirrhosis. Dilutional hyponatremia or rarely low-salt syndrome may develop. Gynecomastia may develop and in rare instances some breast enlargement may persist. Thiazides may alter the metabolism of uric acid and carbohydrates with possible hyperuricemia, gout and decreased glucose tolerance. Vascular responsiveness to norepinephrine is reduced. Thiazides may also increase the responsiveness to tubocurarine. The antihypertensive effects of hydrochlorothiazide may be enhanced in sympathectomized patients. Thiazides may decrease serum PBI levels and prolonged therapy may induce hypercalcemia and hypophosphatemia. Spironolactone may and hydrochlorothiazide does cross the placental barrier. Use in pregnant women requires that the anticipated benefit be weighed against possible hazards to the fetus. Breast feeding should be discontinued when Aldactazide is being used.

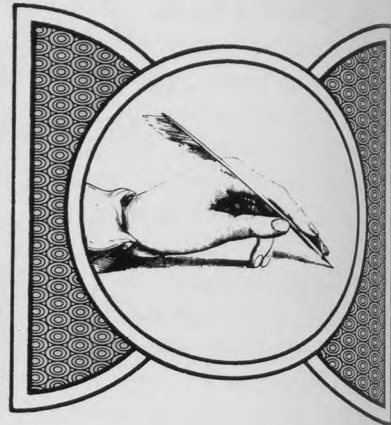
**Adverse Reactions:** *Associated with spironolactone:* Gynecomastia is observed not infrequently. Gastrointestinal symptoms including cramping and diarrhea, drowsiness, lethargy, headache, maculopapular or erythematous cutaneous eruptions, urticaria, mental confusion, drug fever, ataxia, inability to achieve or maintain erection, irregular menses or amenorrhea, postmenopausal bleeding, hirsutism and deepening of the voice. Carcinoma of the breast has been reported but a cause-and-effect relationship has not been established. *Associated with thiazides:* Gastrointestinal symptoms (anorexia, nausea, vomiting, diarrhea, abdominal cramps), purpura, thrombocytopenia, leukopenia, agranulocytosis, dermatologic symptoms (cutaneous eruptions, pruritus, erythema multiforme), paresthesia, acute pancreatitis, jaundice, dizziness, vertigo, headache, xanthopsia, photosensitivity, necrotizing angitis, aplastic anemia, orthostatic hypotension, muscle spasm, weakness and restlessness. Adverse reactions are usually reversible upon discontinuation of Aldactazide.

**SEARLE**

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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.

### Workup for Low Back Pain

To the Editor:

Family Practice Grand Rounds by Davidson et al, "Perinephric Abscess and Chronic Low Back Pain" (*J Fam Pract* 15:1059, 1982), was most interesting. Again we are vividly reminded that the elderly often present in atypical fashion.

However, I found Dr. Daehler's comments concerning the minimum workup of a 59-year-old woman who presents with back pain most unfortunate. Although he concedes "a good examination is the first priority," Dr. Daehler follows that statement with a recommendation for a litany of laboratory tests that would surely impress even the most skeptical internist. An x-ray examination is also mentioned, although with the disclaimer that it "is not necessary on the first visit in all patients with back pain."

It is distressing that not one word of Dr. Daehler's remarks on the minimum workup is devoted to the history. Granted, in the example the patient does not speak English, but does this automatically

preclude obtaining a history, formulating a differential diagnosis, and only then selecting those tests that are truly indicated?

The smorgasbord of laboratory tests advocated as the minimum workup would result in a \$75 to \$125 bill for that patient on her initial office visit. Some might argue this is the cost of emergency room medicine. It may be, but this is a *family medicine* Grand Rounds, with its emphasis on knowledge of the patient and the patient's family and continuity of care. In that respect it is most difficult, if not impossible, to accept Dr. Daehler's recommendations for the minimum workup of back pain in an elderly woman.

I am equally confused by Dr. Daehler's comment about the bone scan. What does he mean by "of more value"? Was he hinting that one should obtain a scan rather than a "routine x-ray examination" if a fracture is suspected? I hope not.

In the future I hope we can maintain a jaundiced eye when reading

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(erythromycin ethylsuccinate)

**INDICATIONS:** *Streptococcus pyogenes* (Group A beta hemolytic streptococcus): Upper and lower respiratory tract, skin, and soft tissue infections of mild to moderate severity.

Injectable benzathine penicillin G is considered by the American Heart Association to be the drug of choice in the treatment and prevention of streptococcal pharyngitis and in long-term prophylaxis of rheumatic fever.

When oral medication is preferred for treatment of the above conditions, penicillin G, V, or erythromycin are alternate drugs of choice.

When oral medication is given, the importance of strict adherence by the patient to the prescribed dosage regimen must be stressed. A therapeutic dose should be administered for at least 10 days.

**Alpha-hemolytic streptococci (viridans group):** Although no controlled clinical efficacy trials have been conducted, oral erythromycin has been suggested by the American Heart Association and American Dental Association for use in a regimen for prophylaxis against bacterial endocarditis in patients hypersensitive to penicillin who have congenital heart disease, or rheumatic or other acquired valvular heart disease when they undergo dental procedures and surgical procedures of the upper respiratory tract. Erythromycin is not suitable for genitourinary or gastrointestinal tract surgery. NOTE: When selecting antibiotics for the prevention of bacterial endocarditis the physician or dentist should read the full joint statement of the American Heart Association and the American Dental Association.

**Staphylococcus aureus:** Acute infections of skin and soft tissue of mild to moderate severity. Resistant organisms may emerge during treatment.

**Streptococcus pneumoniae (Diplococcus pneumoniae):** Upper respiratory tract infections (e.g., otitis media, pharyngitis) and lower respiratory tract infections (e.g., pneumonia) of mild to moderate degree.

**Mycoplasma pneumoniae (Eaton agent, PPL0):** For respiratory infections due to this organism.

**Hemophilus influenzae:** For upper respiratory tract infections of mild to moderate severity when used concomitantly with adequate doses of sulfonamides. (See sulfonamide labeling for appropriate prescribing information). The concomitant use of the sulfonamides is necessary since not all strains of *Hemophilus influenzae* are susceptible to erythromycin at the concentrations of the antibiotic achieved with usual therapeutic doses.

**Tréponema pallidum:** Erythromycin is an alternate choice of treatment for primary syphilis in patients allergic to the penicillins. In treatment of primary syphilis, spinal fluid examinations should be done before treatment and as part of follow-up after therapy.

**Corynebacterium diphtheriae:** As an adjunct to antitoxin, to prevent establishment of carriers, and to eradicate the organism in carriers.

**Corynebacterium minutissimum:** For the treatment of erythrasma.

**Entamoeba histolytica:** In the treatment of intestinal amebiasis only. Extraenteric amebiasis requires treatment with other agents.

**Listeria monocytogenes:** Infections due to this organism.

**Bordetella pertussis:** Erythromycin is effective in eliminating the organism from the nasopharynx of infected individuals, rendering them non-infectious. Some clinical studies suggest that erythromycin may be helpful in the prophylaxis of pertussis in exposed susceptible individuals.

**Legionnaires' Disease:** Although no controlled clinical efficacy studies have been conducted, *in vitro* and limited preliminary clinical data suggest that erythromycin may be effective in treating Legionnaires' Disease.

**CONTRAINDICATIONS:** Erythromycin is contraindicated in patients with known hypersensitivity to this antibiotic.

**PRECAUTIONS:** Erythromycin is principally excreted by the liver. Caution should be exercised in administering the antibiotic to patients with impaired hepatic function. There have been reports of hepatic dysfunction, with or without jaundice occurring in patients receiving oral erythromycin products.

Areas of localized infection may require surgical drainage in addition to antibiotic therapy.

Recent data from studies of erythromycin reveal that its use in patients who are receiving high doses of theophylline may be associated with an increase of serum theophylline levels and potential theophylline toxicity. In case of theophylline toxicity and/or elevated serum theophylline levels, the dose of theophylline should be reduced while the patient is receiving concomitant erythromycin therapy.

**Usage during pregnancy and lactation:** The safety of erythromycin for use during pregnancy has not been established.

Erythromycin crosses the placental barrier. Erythromycin also appears in breast milk.

**ADVERSE REACTIONS:** The most frequent side effects of erythromycin preparations are gastrointestinal, such as abdominal cramping and discomfort, and are dose related. Nausea, vomiting, and diarrhea occur infrequently with usual oral doses.

During prolonged or repeated therapy, there is a possibility of overgrowth of nonsusceptible bacteria or fungi. If such infections occur, the drug should be discontinued and appropriate therapy instituted.

Allergic reactions ranging from urticaria and mild skin eruptions to anaphylaxis have occurred.

There have been isolated reports of reversible hearing loss occurring chiefly in patients with renal insufficiency and in patients receiving high doses of erythromycin.

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articles with similar recommendations concerning "the minimum workup." Let us not forget that the history is the most important element of the minimum workup. And let us demand, as we do in other areas of medicine, that those who propose these so-called minimum workups base their recommendations on scientific rationale and cost effectiveness, and support their claims with documentation from the medical literature.

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### Adolescent Health Care and Family Practice

To the Editor:

Poole and Morrison's recent article<sup>1</sup> reflecting diagnostic information on adolescents collected from 12 family practices in Colorado provides an interesting appendix for the comprehensive summary of ambulatory health care data recently published by the National Center for Health Statistics (NCHS).<sup>2</sup> Unfortunately, because the age groups selected by the National Ambulatory Medical Care Survey (NAMCS) are slightly different (either 11 to 14 years and 15 to 24 years, or less than 15 years and 15 to 24 years, depending on the category) direct comparisons are not possible. However, a brief look at the national data does verify some of the conclusions drawn by the authors.

First, the importance of general practitioners and family physicians in the care of adolescents is confirmed by the fact that patients in both early and late adolescent years get more health care from general practitioners and family

Table 1. Percent of All Patient Visits by Physician Specialty

Specialty	Age (yr)	
	11-14	15-24
General and family practice	35.0	36.9
Internal medicine	3.9	6.2
Pediatrics	30.2	4.7

physicians than any other group of health care providers (Table 1). Moreover, only patients over the age of 65 years have a higher percentage of their health care visits directed by family physicians and general practitioners than the 15- to 24-year-old group (37.1 percent of all visits vs 36.9 percent of all visits). We assume, therefore, that the patients are "voting with their feet" that the family physician and general practitioner's office is the most likely place for them to seek care.

National figures on frequency of specific diagnoses diverge slightly from the authors' data but generally corroborate their conclusions on the importance of certain specific adolescent health care issues (Table 2). One of the most interesting statistics emerging from the national data and echoed in the authors' study is the high percentage of adolescents who visit a physician for a "general medical examination" (NCHS terminology) or "general health maintenance" (authors' terminology). This is exciting in that adolescence is a crucial time for inculcating good health, diet, and exercise habits and this can often be most successfully done during the "general" health care evaluation and examination.

For those of us who confine our professional lives to the care of

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# Diet & Diabinese®

(chlorpropamide) Tablets  
100 mg and 250 mg

## A proven regimen for effective control of blood sugar.

### BRIEF SUMMARY DIABINESE® (chlorpropamide) Tablets

**Contraindications:** Diabinese is not indicated in patients having juvenile or growth-onset diabetes mellitus, severe or unstable "brittle" diabetes, and diabetes complicated by ketosis and acidosis, diabetic coma, major surgery, severe infection, or severe trauma. Diabinese is contraindicated during pregnancy. Serious consideration should be given to the potential hazard of its use in women of childbearing age who may become pregnant.

Diabinese is contraindicated in patients with serious impairment of hepatic, renal, or thyroid function.

**Precautions:** Use chlorpropamide with caution with barbiturates, in patients with Addison's disease or in those ingesting: alcohol, antibacterial sulfonamides, thiazides, phenylbutazone, salicylates, probenecid, dicoumarol or MAO inhibitors. Adequate dietary intake should be assured in all patients using Diabinese.

**Warnings:** DIABINESE (CHLORPROPAMIDE) SHOULD NOT BE USED IN JUVENILE DIABETES OR IN DIABETES COMPLICATED BY ACIDOSIS, COMA, SEVERE INFECTION, MAJOR SURGICAL PROCEDURES, SEVERE TRAUMA, SEVERE DIARRHEA, NAUSEA AND VOMITING, ETC. HERE, INSULIN IS INDISPENSABLE.

HYPOGLYCEMIA, IF IT OCCURS, MAY BE PROLONGED. (SEE ADVERSE REACTIONS.) IN INSTANCES OF CONCOMITANT USE WITH INSULIN, PATIENTS SHOULD BE CAREFULLY MONITORED.

**Adverse Reactions:** Usually dose-related and generally respond to reduction or withdrawal of therapy. Generally transient and not of a serious nature and include anorexia, nausea, vomiting and gastrointestinal intolerance; weakness and paresthesias.

Certain untoward reactions associated with idiosyncrasy or hypersensitivity have occasionally occurred, including jaundice, skin eruptions rarely progressing to erythema multiforme and exfoliative dermatitis, and probably depression of formed elements of the blood. They occur characteristically during the first six weeks of therapy. With a few exceptions, these manifestations have been mild and readily reversible on the withdrawal of the drug. The more severe manifestations may require other therapeutic measures, including corticosteroid therapy. Diabinese should be discontinued promptly when the development of sensitivity is suspected.

Jaundice has been reported, and is usually promptly reversible on discontinuance of therapy. THE OCCURRENCE OF PROGRESSIVE ALKALINE PHOSPHATASE ELEVATION SHOULD SUGGEST THE POSSIBILITY OF INCIPIENT JAUNDICE AND CONSTITUTES AN INDICATION FOR WITHDRAWAL OF THE DRUG. Leukopenia, thrombocytopenia and mild anemia, which occur occasionally, are generally benign and revert to normal, following cessation of the drug.

Cases of aplastic anemia and agranulocytosis, generally similar to blood dyscrasias associated with other sulfonylureas, have been reported.

BECAUSE OF THE PROLONGED HYPOGLYCEMIC ACTION OF DIABINESE, PATIENTS WHO BECOME HYPOGLYCEMIC DURING THERAPY WITH THIS DRUG REQUIRE CLOSE SUPERVISION FOR A MINIMUM PERIOD OF 3 TO 5 DAYS, during which time frequent feedings or glucose administration are essential. The anorectic patient or the profoundly hypoglycemic patient should be hospitalized.

Rare cases of phototoxic reactions have been reported. Edema associated with hyponatremia has been infrequently reported. It is usually readily reversible when medication is discontinued.

**Dosage:** The total daily dosage is generally taken at a single time each morning with breakfast. Occasionally, cases of gastrointestinal intolerance may be relieved by dividing the daily dosage. A LOADING OR PRIMING DOSE IS NOT NECESSARY AND SHOULD NOT BE USED. The mild to moderately severe, middle-aged, stable diabetic should be started on 250 mg daily. Because the geriatric diabetic patient appears to be more sensitive to the hypoglycemic effect of sulfonylurea drugs, older patients should be started on smaller amounts of Diabinese, in the range of 100 to 125 mg daily.

After five to seven days following initiation of therapy, dosage may be adjusted upward or downward in increments of 50 to 125 mg at intervals of three to five days. PATIENTS WHO DO NOT RESPOND COMPLETELY TO 500 MG DAILY WILL USUALLY NOT RESPOND TO HIGHER DOSES. Maintenance doses above 750 mg daily should be avoided.

**Supply:** 100 mg and 250 mg, blue, 'D'-shaped, scored tablets.

More detailed professional information available on request.

**Pfizer** LABORATORIES DIVISION  
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Leaders in Oral Diabetic Therapy

## LETTERS TO THE EDITOR

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adolescents and the training of those who will continue this care, the message from the NAMCS is inescapable: If we are really interested in providing the best health care possible for adolescents and young adults, and if we have a special interest in training those who will provide care to this group, we must align ourselves with family practice programs and participate actively in the training of family physicians. We can only hope that our peers involved in organizing and directing family practice programs will appreciate our interest

and recognize that we have something special to offer.

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### References

1. Poole SR, Morrison JD: Adolescent health care in family practice. *J Fam Pract* 16:103, 1983
2. Gagnon RO, DeLuzier JE, McLemore T: National ambulatory medical care survey, United States, 1979 summary. In National Center for Health Statistics (Hyattsville, Md): *Vital and Health Statistics*, series 13, No. 66. DHHS publication No. (PHS) 82-1727. Government Printing Office, 1982

Table 2. Rank Order of Adolescent Diagnoses

Poole and Morrison <sup>1</sup>		NAMCS <sup>2</sup>	
Diagnoses	Percent of All Diagnoses	Diagnoses	Percent of All Diagnoses
1. Obstetrical care	15.9	1. Normal pregnancy	11.9
2. General health maintenance	13.3	2. General medical examination	5.1
3. Upper respiratory tract infection	8.4	3. Acne	4.0
4. Sprain	4.2	4. Sprains	3.8
5. Contraception	3.1	5. Allergic rhinitis	2.6
6. Laceration	2.7	6. Upper respiratory tract infection	2.2
7. Pharyngitis	2.3	7. Inflammatory disease—female pelvis	2.2
8. Abdominal pain	1.8	8. Neurotic and personality disorder	2.1
9. Acne	1.8	9. Pharyngitis	1.8
10. Cystitis	1.7	10. Disorders of refraction	1.8
11. Bruise/contusion	1.7	11. Tonsillitis	1.5
12. Vaginitis	1.7	12. Viral warts	1.5
13. Fracture	1.7	13. Contraception	1.4
14. Menstrual disorders	1.6	14. Fracture of upper limb	1.3
15. Warts	1.6	15. Rheumatism	1.3
16. Bronchitis	1.4	16. Obesity	1.3
17. Hay fever	1.4	17. Allergy, unspecified	1.2
18. Acute otitis media	1.3	18. Bronchitis	1.2
19. Headache	1.2	19. Open wound	1.1
20. Viral syndrome	1.1	20. Contact dermatitis and eczema	1.1