

# Aldactazide®

(spironolactone 25 mg/  
hydrochlorothiazide 25 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 under *Indications*. 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.

**Indications:** Cirrhosis of the liver accompanied by edema and/or ascites. Essential hypertension, edema of congestive heart failure and the nephrotic syndrome, when other measures are considered inappropriate.

**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. 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. 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.

## Dosage and Administration

**Edema in adults:** The usual maintenance dose is one tablet four times daily but may range from one to eight tablets daily depending on the response to the initial titration.

**Edema in children:** The usual daily maintenance dose should be that which provides 0.75 to 1.5 mg. of spironolactone per pound of body weight (1.65 to 3.3 mg./kg.).

**Essential hypertension:** Usually two to four tablets daily depending on results of the titration of the individual ingredients.

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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.

## Evaluation of Physicians

To the Editor:

As health-care providers and occasional patients, we have read "In-Training Residency Evaluation" by John B. Corley, MD (J Fam Pract 3:499-504, 1976) with concern and outrage. The subject of the article is commendable, ie, physician-in-training evaluation, which is sub-optimal in all fields of medical training. But the proposed method of evaluation contains an omission that reveals the elitist and self-serving nature of medical practice in this country: in no way are the patients upon whom the residents learn involved in the evaluation of the resident's "professional knowledge, skills, and attitudes." Patients are mentioned in only one area as active evaluators, and this suggestion is not surprisingly introduced with caution: "Attending physicians in the clinics, clinical faculty, and senior house-staff on the wards, preceptors who have residents in their practices, nurses who work with the residents in their offices, *even patients themselves* (italics ours), are all sources of useful data on performance." Nowhere else is patient participation so much as mentioned. One look at the various illustrative charts accompanying the article emphasizes the total exclusion of the patient from the evaluation of his/her doctor-in-training.

If this article represented an isolated point of view or policy in the American health-care system, it might be taken less seriously. Tragically (for the patient!), this is not the case. Health care in the United States is consciously one-sided, with the physician as the active participant and the patient as the passive recipient. Patients are, with few exceptions, not regularly and meaningfully involved in the maintenance of their own health. As this article clearly demonstrates, the opinion of the patient concerning the care which only he/she experiences is considered irrelevant!

Do physicians believe that patients have no right to contribute to the evaluation of their professional skills and attitudes? Do physicians believe patients are not capable of thoughtful analysis? Does the patient exist for the purpose of training a resident, or does the resident exist for the purpose of serving the patient?

We believe that patients have not only the ability but also the right and obligation to participate in the evaluation of physicians-in-training. Indeed, *only* the patients are in a position to give feedback in several areas of physi-

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