

The ad suggests that any physician taking a patient off a thiazide-potassium combination may wish to consider Enduron as alternative therapy. It states that the product will "do an outstanding job for you, *without* routine potassium supplementation," and that it has "potassium-sparing characteristics." The FDA believes that these claims could lead to the erroneous conclusion that hypokalemia is less likely to occur, and consequently, that potassium supplementation is less often necessary with Enduron than with other thiazides.

In point of fact, the need to consider proper potassium supplementation, dietary or otherwise, is no less with Enduron or Enduronyl than with any other thiazide drug.

Because the ad's "brief summary" of warning information was considered inadequate, a new one is enclosed. The information capitalized in the attached revised "brief summary" is not present in current ads, but will be incorporated into future ads for these products.

ABBOTT LABORATORIES.

BRIEF SUMMARY

ENDURON AND ENDURONYL

(NOTE.—This revised "brief summary" for use in future medical journal advertising contains additional phrases and items (printed in capital letters) from the official package insert which remains unchanged.)

Indications.—Enduron is used to control edema and mild to MODERATE hypertension; also used with other drugs for hypertension. Enduronyl is used in mild to moderately severe hypertension; WHEN USED WITH ENDURONYL, MORE POTENT AGENTS CAN BE GIVEN AT REDUCED DOSAGE TO MINIMIZE UNDESIRABLE SIDE EFFECTS.

Contraindications.—Neither Enduron nor Enduronyl should be used in severe renal disease (except nephrosis) or shutdown; in severe hepatic disease or impending hepatic coma; in patients sensitive to thiazides. HEPATIC COMA HAS BEEN REPORTED AS A RESULT OF HYPOKALEMIA IN PATIENTS RECEIVING THIAZIDES. Enduronyl is contraindicated in patients with severe mental depression and SUICIDAL TENDENCIES, active peptic ulcer, or ulcerative colitis.

Warnings.—Consider possible sensitivity reactions in patients with a history of allergy or asthma. If added potassium intake is indicated, dietary supplementation is recommended. Enteric-coated potassium tablets should be reserved for cautious use only when adequate dietary supplementation is not practical because these tablets may induce serious or fatal small bowel lesions CONSISTING OF STENOSIS WITH OR WITHOUT ULCERATION. THESE SMALL BOWEL LESIONS HAVE CAUSED OBSTRUCTION, HEMORRHAGE AND PERFORATION FREQUENTLY REQUIRING SURGERY. MEDICATION SHOULD BE DISCONTINUED IMMEDIATELY IF ABDOMINAL PAIN, DISTENSION, NAUSEA, VOMITING OR GASTROINTESTINAL BLEEDING OCCURS.

Precautions.—Use thiazides with caution in severe renal dysfunction, impaired hepatic function, or progressive liver disease. In surgical patients, thiazides may REDUCE the response to vasopressors and INCREASE the response to tubocurarine. Use thiazides with caution in pregnancy (bone marrow depression, thrombocytopenia, or altered carbohydrate metabolism HAVE BEEN REPORTED in certain newborn infants). Blood dyscrasias INCLUDING THROMBOCYTOPENIA WITH PURPURA, AGRANULOCYTOSIS AND APLASTIC ANEMIA; elevations of BUN, serum uric acid, or blood sugar HAVE ALSO BEEN REPORTED. SYMPTOMATIC GOUT MAY BE INDUCED. ANTIHYPERTENSIVE RESPONSE MAY BE ENHANCED FOLLOWING SYMPATHECTOMY. Use Enduronyl with caution in patients with a history of peptic ulcer, as rauwolfias may increase gastric secretion. Discontinue at the first sign of mental depression. Rauwolfia alkaloids may increase hypotensive effects of surgery or anesthesia, and SHOULD BE discontinued two weeks prior. THEY ALSO LOWER THE CONVULSIVE THRESHOLD AND SHORTEN SEIZURE LATENCY. IN EPILEPSY DOSAGE ADJUSTMENT OF ANTICONVULSANT MEDICATION MAY BE NECESSARY. Alcohol, barbiturates, or narcotics may potentiate action of deserpidine.

Adverse reactions.—During intensive or prolonged therapy, GUARD AGAINST HYPOCHLOREMIC ALKALOSIS AND HYPOKALEMIA (especially the latter if patient is on digitalis). ALL PATIENTS SHOULD BE OBSERVED FOR SIGNS OF HYPONATREMIA ("LOW-SALT" SYNDROME). REPORTED