Aldactide®

Brand of spironolactone B.P. with hydroflumethiazide.

2 **Composition**
ALDACTIDE 25 tablets contain 25mg spironolactone B.P. with 25mg hydroflumethiazide B.P.
ALDACTIDE 50 tablets contain 50mg spironolactone B.P. with 50mg hydroflumethiazide B.P.

5 **Indications**
The treatment of essential hypertension; oedema and ascites of congestive heart failure; cirrhosis of the liver; the nephrotic syndrome and idiopathic oedema.
Aldosterone may be an etiologic factor in some cases involving malignant effusions and beneficial results have been reported with the use of Aldactide.

10 **Dosage and Administration**
Adults:
For Hypertension: Two to four tablets Aldactide 25 daily, or one to two tablets Aldactide 50 daily, will be adequate for most patients provided treatment is continued for two weeks or longer. The dosage of other antihypertensive drugs should first be decreased by at least 50% when Aldactide is added to the regimen, and then adjusted as necessary. Treatment may be given as single or divided doses.
For Oedematous Conditions: A daily dosage of four tablets Aldactide 25 or two tablets Aldactide 50 will be adequate for most patients provided treatment is continued for two weeks or longer but dosage may range between 25mg and 200mg daily. Treatment may be given as single or divided doses.
Children
For oedema in children, the usual daily maintenance dose of Aldactide should be that which provides 0.75 to 1.5mg of spironolactone per pound of body weight (1.65 to 3.3mg/kg).

6 **Contra-Indications**
Acute renal insufficiency, significant impairment of renal function, anuria, hyperkalemia or sensitivity to spironolactone, thiazide diuretics or to other sulfonamide-derived drugs.

7 **Warnings**
Since spironolactone is a potassium-sparing diuretic, the concomitant administration of potassium supplements or of other potassium-sparing agents is not recommended as it may induce hyperkalemia.
Sulfonamide derivatives, including thiazides, have been reported to exacerbate or activate systemic lupus erythematosus.

8 **Precautions**
Periodic estimation of serum electrolytes is desirable due to the possibility of hyperkalemia, hyponatremia and possible transient BUN elevation, especially in patients with preexisting impaired renal function, in whom the risk/benefit ratio should always be weighed. Caution should be used in treating patients with acute or severe hepatic failure, especially patients with lower effective plasma volume. There may also be an increased potential to precipitate hepatic coma in such patients.
Both spironolactone and the thiazides reduce the vascular responsiveness of norepinephrine. Therefore, caution should be exercised in the management of patients subjected to regional or general anesthesia while they are being treated with Aldactide.
As carbenoxolone may cause sodium retention and thus decrease the effectiveness of Aldactide, concurrent use of the two agents should be avoided.
Reversible hyperchloremic metabolic acidosis, usually in association with hyperkalemia, has been reported to occur in some patients with decompensated hepatic cirrhosis, even in the presence of normal renal function.
Spironolactone has been shown to increase the half-life of digoxin. This may result in increased serum digoxin levels and subsequent digitalis toxicity. It may be necessary to reduce the maintenance and digitalization doses when spironolactone is administered, and the patient should be carefully monitored to avoid over- or underdigitalization.
Several reports of possible interference with digoxin radio-immunoassays by spironolactone, or its metabolites, have appeared in the literature. Neither the extent nor the potential clinical significance of its interference (which may be assay-specific) has been fully established.

Usage in Pregnancy
Spironolactone or its metabolites may, and thiazides do, cross the placental barrier. Therefore, the use of Aldactide in pregnant women requires that the anticipated benefit be weighed against possible hazards to the mother and fetus.

Nursing Mothers
Thiazides, as well as canrenone, a metabolite of spironolactone, appear in breast milk. If use of the drug is deemed essential, an alternative method of infant feeding should be instituted.

Animal Findings
In chronic toxicity studies in rats, spironolactone has been shown to produce tumors when administered at high doses of 25 to 250 times the usual daily human dose over long period of time. The significance of these findings with respect to clinical use is not certain. It has been demonstrated that the disposition and metabolism of spironolactone in rats is different from man.

9 **Adverse Reactions**
Gynecomastia may develop in association with the use of spironolactone, and physicians should be alert to its possible onset. The development of gynecomastia appears to be related to both dosage level and duration of therapy and is normally reversible when Aldactide is discontinued. In rare instances some breast enlargement may persist.
Other adverse effects associated with the use of spironolactone are infrequent and include: 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, and post-menopausal bleeding.
Adverse reaction reported in association with the use of thiazides include: 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. Thiazides have been reported to decrease glucose tolerance and to induce hyperuricemia.
Adverse reactions are usually reversible upon discontinuation of Aldactide.
A few cases of agranulocytosis have been reported in patients taking spironolactone.

1 **Presentation**
Aldactide 25: Packs of 40, 100 or 500.
Aldactide 50: Packs of 40, 100 or 500.
(22)

25mg 40 n°: 2202567 2/84
" 100 : 2202567 3/84
50mg 28 : 2202567 4/84
100 : 2202567 6/

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