90 mm

215 mm

Spiromide® *Tablets*

(Spironolactone B.P. and Furosemide Ph. Eur.)

PRESENTATION AND COMPOSITION
SPIROMIDE:
Pink colored, biconvex film coated tablets engraved "SEARLE" on one side with a break line on other side, each containing 50 mg Spironolactone (B.P.) and 20 mg Furosemide (Ph. Eur.)

SPIROMIDE 40:
Orangish pink colored biconvex film coated tablets engraved "SEARLE" on one side with a break line on other side, each containing 50 mg Spironolactone (B.P.) and 40 mg Furosemide (Ph. Eur.)

PHARMACOLOGY :
Furosemide is extensively bound to plasma proteins, mainly to albumin. Plasma concentrations ranging from 1 to 400 µg/mL are 91 to 99% bound in healthy individuals. The unbound fraction averages 2.3 to 4.1% at therapeutic concentrations.The onset of diuresis following oral administration is within 1 hour. The peak effect occurs within the first or second hour. The duration of diuretic effect is 6 to 8 hours.

Spironolactone is rapidly and extensively metabolize and its metabolites are more than 90% bound to plasma proteins. The metabolites are excreted primarily in the urine and secondarily in bile. Through its action in antagonizing the effect of aldosterone, Spironolactone inhibits the exchange of sodium for potassium in the distal renal tubule and helps to prevent potassium loss. Spironolactone has not been demonstrated to elevate serum uric acid, to precipitate gout, or to alter carbohydrate metabolism.

ACTIONS
Spironolactone in concomitant therapy with Furosemide is especially useful in edematous states as it enhances the diuresis, blocks the effects of secondary hyperaldosteronism and minimizes potassium deficiency thus obviating the need for potassium supplements.

INDICATIONS
Edematous conditions especially those in which secondary hyperaldosteronism is involved, edema and ascites of congestive heart failure and cirrhosis of the liver. SPIROMIDE is also indicated in the management of mild to moderate essential hypertension and the nephrotic syndrome.

CONTRAINDICATIONS
Acute renal insufficiency, significant deterioration of renal function, anuria, hyperkalaemia, and in patients with a history of hypersensitivity, to Furosemide or Spironolactone.

WARNINGS
The administration of potassium supplements or other potassium sparing agents is not recommended as they may induce hyperkalaemia. An adjustment in the dosage of cardiac glycosides and anti hypertensive drugs may be necessary when Spiromide is added to the regimen.
Sulfonamide derivatives, including Furosemide, have been reported to exacerbate or activate systemic lupus erythematosus.

PRECAUTIONS
Periodic estimation of serum electrolytes is desirable due to the possibility of hyperkalaemia, hyponatraemia, hypochloremic alkalosis and possible transient BUN elevation, especially in patients with preexisting impaired renal function. Should hyperkalaemia develop, Spiromide should be discontinued and active measures taken to reduce serum-potassium to normal. In common with thiazide diuretics, SPIROMIDE may elevate serum uric acid levels and precipitate gout. Caution should be observed in patients with severe liver diseases as over vigorous diuretic therapy may precipitate encephalopathy in susceptible patients, increases blood glucose and alterations in glucose tolerance have been reported in some cases with Furosemide. Periodic checks on urine and blood glucose should be made in diabetics and even those suspected of latent diabetes when receiving SPIROMIDE. Furosemide increases the risk of acute urinary retention in patients with prostatic hypertrophy and or with impairment of micturition. Reversible hyperkalemia metabolic acidosis has been reported to occur in some patients with decompensate hepatic cirrhosis.

Spironolactone or its metabolites may cross the placental barrier and the safety of Furosemide in early pregnancy has not been established. Therefore, the use of SPIROMIDE in pregnant women requires that the anticipated benefit be weighed against possible hazard to the mother and fetus. Canrenone, a metabolite of Spironolactone and Furosemide appear in breast milk. Furosemide may inhibit lactation if the use of SPIROMIDE in nursing mothers is deemed essential; an alternative method of irritant feeding should be instituted.

ADVERSE REACTIONS
Gynaecomastia may develop in association with use of Spironolactone, and physicians should be alert to its possible onset. The development of Gynaecomastia appears to be related to both dosage level and duration of therapy and is normally reversible when Spironolactone is discontinued. In rare instances some breast enlargement may persist. Other reactions, usually reversible upon discontinuance of drug have been reported including: impotence, gastrointestinal intolerance, drowsiness, cutaneous eruptions, menstrual irregularities and mild androgenic effects.

Furosemide may cause azotemia, hyperuricaemia and hyperglycaemia. Bone marrow depression has been reported as a rare complication of Furosemide therapy which necessitates withdrawal of treatment. Dermatological reactions have been reported with the use of Furosemide, including urticaria, erythema multiforme, purpura. exfoliative dermatitis, pruritis, necrotizing angilitis and phototoxic blisters. Hematological disturbances with Furosemide include anaemia, agranulocytosis and thrombocytopenia. Allergic interstitial nephritis and acute pancreatitis have been reported rarely.

Other reactions, usually reversible upon discontinuance of Furosemide have been reported including: tinnitus and reversible deafness, paresthesia, blurring of vision, postural hypotension and gastrointestinal intolerance.

DOSAGE AND ADMINISTRATION
SPIROMIDE
From one to four tablets daily (50 to 200 mg of Spironolactone and 20 to 80 mg of Furosemide) according to the patient's response.

SPIROMIDE 40:
For previously stabilized patients requiring higher dosage of Spironolactone and Furosemide, SPIROMIDE 40 tablets can, be used at a dosage of 1-2 tablets daily (50 mg - 100 mg of Spironolactone and 40-80 mg Furosemide.)

INTERACTIONS:
Furosemide and salicylates compete at the renal excretory sites; therefore, patients receiving high doses of salicylates may experience salicylate toxicity.

Furosemide antagonizes tubocurarine and may potentiate the action of succinylcholine. Both Spironolactone and Furosemide reduce the vascular responsiveness to norepinephrine. Therefore caution should be exercised in patients subjected to local or general anesthesia. The renal clearance of lithium is reduced by Furosemide which may result in added risk of lithium toxicity.

INSTRUCTIONS:
To be sold on prescription of a registered medical practitioner only.
Protect from moisture,freezing, excessive heat and sunlight.
Store below 30°C.
Keep out of the reach of children.

PACKAGE QUANTITY

SPIROMIDE	: Boxes of 20 tablets (2 x 10's blister Strips)
SPIROMIDE 40	: Boxes of 30 tablets (3 x 10's blister Strips)

Mfg. Searle Specs.

SEARLE

Manufactured by:
The Searle Company Limited
F-319, S.I.T.E., Karachi-Pakistan.

1548600202