1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

SPIRACTIN (tablets)

COMPOSITION

SPIRACTIN contains 25 mg of spironolactone.

Excipients:

Lactose monohydrate, magnesium stearate, polysorbate 80, povidone K25, sodium starch glycolate, maize starch.

Contains sugar: Lactose monohydrate 140 mg

CATEGORY AND CLASS

A 18.1 Diuretics

PHARMACOLOGICAL ACTION

Spironolactone blocks the sodium retaining action of aldosterone on the distal convoluted renal tubule, and thereby increases urinary excretion of sodium and chloride; however, it reduces excretion of potassium and ammonium and decreases the titrable acidity of urine.

INDICATIONS

Spironolactone may be used initially in the treatment of patients with oedema and ascites associated with hepatic cirrhosis to avoid depletion of potassium or precipitation of hepatic coma that may follow use of a thiazide diuretic. If more profound diuresis is necessary, or in patients with congestive heart failure and the nephrotic syndrome, a thiazide or other diuretics may be given concomitantly with spironolactone.

Spironolactone may be effective in treating patients who do not respond satisfactorily to other diuretic agents but it is most useful when given with another diuretic.

Spironolactone is reported to have a hypotensive effect in patients with essential hypertension. The rise in serum potassium levels produced by spironolactone in patients with primary hyperaldosteronism has been used as an aid in the diagnosis of this affliction.

CONTRAINDICATIONS

Spironolactone is contraindicated in patients with acute renal insufficiency, anuria and hyperkalaemia.

WARNINGS AND SPECIAL PRECAUTIONS

Because of the risk of producing hyperkalaemia, spironolactone should be given with caution to patients with impaired renal function. It should only be given under careful supervision in patients with severe hepatic disease as stupor and transient hepatic coma may develop in these patients.

Plasma electrolyte determinations must be carried out during treatment to prevent electrolyte imbalance, especially hyponatraemia and hyperkalaemia.

Potassium supplementation in the form of either medication or a potassium-rich diet should not be given. Such supplementation can cause hyperkalaemia.

Excipients

Contains lactose which may have an effect on the glycaemic control of patients with diabetes mellitus.

Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take SPIRACTIN.

INTERACTIONS

Spironolactone may enhance the effects of other antihypertensive agents, the dose of which may need to be reduced. It should be given with caution with other potassium sparing medicines. Serum electrolytes should be estimated periodically.

HUMAN REPRODUCTION

Safety in pregnancy has not been established.

DOSAGE AND DIRECTIONS FOR USE

The initial dosage is 100 mg daily in 4 divided doses. After 5 days the effect is evaluated; if the response is satisfactory the medicine is continued, if possible at a lower dose. If the response is not satisfactory, a conventional diuretic may be given concomitantly at usual doses. In certain circumstances the dose of spironolactone may have to be increased to 400 mg daily. On discontinuing the medicine the dose should be gradually decreased.

SIDE EFFECTS

Hyperkalaemia and hyponatraemia have been observed in patients treated with spironolactone. Drowsiness, headache, ataxia, coma, maculopapular or erythematous cutaneous eruptions, impotence, gynecomastia, mild androgenic effect including hirsutism, irregular menses and deepening voice may occur occasionally.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

The symptoms of overdosage are hyperkalaemia clinically characterised by paralysis or muscle spasm.

Treatment is symptomatic with emphasis on potassium excretion.

IDENTIFICATION

White, round biconvex tablets, bisected on one side and plain on the other side.

PRESENTATION

30 or 200 tablets together with a rayon insert are packed in a white propylene container with a low-density polyethylene cap.

28 or 84 tablets are packed in a layflat metallised polyester laminated and sealed with an opaque linear low-density polyethylene Ziploc.

30 tablets are packed in a clear polyvinyl chloride film coated with polyvinylidenechloride and sealed with a silver, aluminium foil backing. The blister strips are packed into an outer cardboard carton.

30 tablets are packed in a clear polyvinylchloride film and sealed with a silver, aluminium foil backing. The blister strips are packed into an outer cardboard carton.

Not all packs and pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C. Protect from light.

Keep in the original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

L/18.1/186

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

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Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

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