1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS S3

PROPRIETARY NAME AND DOSAGE FORM

SPIRACTIN 100 TABLETS

COMPOSITION

SPIRACTIN 100 TABLETS contain 100 mg of spironolactone.

Excipients:

Croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone K25, purified talc, sodium lauryl sulphate, starch

Contains sugar: Lactose monohydrate 237 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.

CONTRAINDICATIONS

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

SPIRACTIN 100 TABLETS should not be given with other potassium-sparing diuretics or potassium-supplements. Safety in pregnancy has not been established.

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 and blood-urea-nitrogen determinations must be carried out during treatment to prevent electrolyte imbalance, especially hyponatraemia and 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 100 TABLETS.

INTERACTIONS

Spironolactone may enhance the effects of other antihypertensive agents, the dose of which may need to be reduced. Serum electrolytes should be estimated periodically.

SPIRACTIN 100 TABLETS should be given with care to patients with diabetes mellitus and patients likely to develop acidosis.

HUMAN REPRODUCTION

Safety in pregnancy has not been established.

DOSAGE AND DIRECTIONS FOR USE

The initial dosage is 100 mg daily. 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 tablet.

PRESENTATION

30, 60 or 200 tablets are packed into a white polypropylene (PP) securitainer with a white low density polyethylene (LDPE) closure, together with a foam insert.

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

U/18.1/52

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

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

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

Date of registration: 18 July 1988

Date of the most recently revised professional information as approved by the Authority:

18 July 1988

Namibia: NS2 90/18.1/001198

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