1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

PURESIS (tablet)

COMPOSITION

Each tablet of PURESIS contains 40 mg furosemide.

Excipients:

Magnesium stearate, microcrystalline cellulose, modified cellulose gum, purified talc, starch maize, sodium bicarbonate

Sugar free

CATEGORY AND CLASS

A 18.1 Diuretics

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Furosemide exerts its diuretic action by virtue of its saluretic properties. Experimental evidence has proved that furosemide acts by reducing the reabsorption of sodium and water at the levels of the proximal convoluted tubule, ascending limb of Henle's loop and the distal convoluted

tubule.

Pharmacokinetic properties

Furosemide thus acts throughout the tubule, and it is today believed that the action of Furosemide on the Loop of Henle is the most important action on the nephron. In situations where other methods of treatment fail to induce diuresis, it is often possible, with furosemide, to increase the excretion of sodium and water, even when the glomerular filtration rate is markedly impaired.

Furosemide lowers pathologically raised blood pressure levels but does not affect normal values.

With furosemide administration, the onset of action is rapid, usually within half-an-hour. Peak action is usually achieved after 2 hours, and the duration of action of the drug is 4 to 5 hours.

INDICATIONS

(a) Ascites due to cirrhosis of the liver, mechanical obstruction or cardiac failure.

(b) To prevent oliguria from progressing to complete anuria.

(c) Cardiac oedema.

(d) Hypertension of mild to moderate degree.

(e) Oedema occurring during the last three months of pregnancy - pre-eclamptic toxaemia and eclampsia (see WARNINGS AND SPECIAL PRECAUTIONS).

CONTRAINDICATIONS

Patients who exhibit hypersensitivity to furosemide.

In hepatic coma and in states of electrolyte depletion. PURESIS is contraindicated if increasing azotaemia and oliguria treatment of severe progressive renal disease.

Lactating women (see HUMAN REPRODUCTION).

WARNINGS AND SPECIAL PRECAUTIONS

In pregnancy, PURESIS should be administered with great caution and only in carefully selected cases, for short periods of time (see HUMAN REPRODUCTION).

PURESIS should be used with care in patients with prostatic hypertrophy or impairment of micturition.

PURESIS should be used with caution in patients with impaired hepatic function since it may increase the risk of hepatic encephalopathy. It should be used with caution in patients with renal impairment.

The use of PURESIS in patients suffering from acute forms of porphyria, especially variegate porphyria, and to a lesser extent acute intermittent porphyria and hereditary coproporphyria is contentious, and PURESIS should thus be used with caution in these patients.

Excessive diuresis may result in dehydration and reduction in blood volume, with circulatory collapse and the possibility of vascular thrombosis and embolism, particularly in elderly patients. The excessive loss of potassium in patients receiving cardiac glycosides may precipitate digitalis toxicity. Care should be taken in patients receiving potassium depleting steroids.

Electrolyte disturbance - Hypokalaemia may be reduced with a potassium-rich diet.

If it already exists before the commencement of treatment - which is particularly likely to occur in cases of cirrhosis - the serum potassium should be restored to normal by potassium supplements and, if necessary, by the administration of sodium and chloride. Because of its strong natriuretic effect, PURESIS may cause a decrease in the sodium levels, particularly when the oedema is corrected rapidly.

Electrolyte depletion may manifest itself by weakness, dizziness, lethargy, leg cramps, anorexia, vomiting and/or mental confusion.

Effects on ability to drive and use machines

Not known.

INTERACTIONS

Concomitant therapy with cephaloridine may result in nephrotoxicity.

PURESIS may enhance the nephrotoxicity of cephalosporin antibiotics such as cephalothin and of aminoglycoside antibiotics.

It can also enhance the ototoxicity of aminoglycoside antibiotics. Concurrent administration of phenytoin or indomethacin may reduce the clinical effects of PURESIS.

PURESIS may enhance the toxicity of digitalis glycosides by depleting serum-potassium

concentrations.

It may enhance the neuromuscular blocking action of competitive muscle relaxants, such as tubocurarine.

It may enhance the effects of antihypertensive agents.

The potassium-depleting effect of furosemide may be enhanced by corticosteroids, corticotrophin, or carbenoxolone.

Concomitant administration of PURESIS and lithium is generally not recommended since the association may lead to toxic blood concentrations of lithium.

Blood-glucose concentrations should be monitored in patients taking antidiabetic agents as requirements may change.

HUMAN REPRODUCTION

In pregnancy, PURESIS should be administered with great caution and only in carefully selected cases, for short periods of time.

Lactating women should not use PURESIS (see CONTRAINDICATIONS and WARNINGS AND SPECIAL PRECAUTIONS).

DOSAGE AND DIRECTIONS FOR USE

Adults Initial dose: One to three tablets.

Maintenance dose: Half to one tablet daily.

Or: As prescribed by the physician.

SIDE EFFECTS

(i) Various forms of dermatitis including urticaria and exfoliative dermatitis, pruritus, paraesthesia, blurring of vision, yellow vision, dizziness, pancreatitis, photosensitivity, postural hypotension, headache, nausea, vomiting or diarrhoea may occur.

(ii) Anaemia, leucopenia, aplastic anaemia and thrombocytopenia (with purpura) may occur. Agranulocytosis has occurred.

(iii) Asymptomatic hyperuricaemia can occur and gout may be precipitated.

(iv) Alterations in glucose tolerance tests with abnormalities of the fasting and 2-hour post-prandial sugar has been observed, and cases of precipitation of diabetes mellitus have been reported.

(v) PURESIS may lower the serum calcium levels and cases of tetany have been reported.

Hepatic dysfunction, cholestatic jaundice and paraesthesia have been reported. Tinnitus and deafness may occur in particular during rapid high-dose parenteral furosemide therapy. Deafness may be permanent particularly if furosemide has been given to patients taking ototoxic medication.

PURESIS increases the urinary excretion of calcium. Renal stone formation has been reported when PURESIS has been used to treat preterm infants.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Symptoms

See SIDE EFFECTS above.

Treatment

Treatment is symptomatic and supportive.

IDENTIFICATION

A flat, white to off-white bevel edged bisected tablet engraved F above the bisect and 1 below the bisect. “F/1” on one side and plain on the other side.

PRESENTATION

30 or 250 tablets are packed in a white opaque high density polyethylene plastic container with a white opaque high density polyethylene screw closure with a 3 layered induction seal liner.

30 or 250 tablets are packed in a round amber high density polyethylene plastic container with an amber high density polyethylene screw closure with a 3 layered induction seal liner.

250 tablets are packed in a white polypropylene securitainer with low linear density polyethylene closures.

30 tablets are packed in a red polyvinylchloride/polyvinylidene chloride blister strips sealed with an aluminium foil backing. Blisters are packed into a 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 original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

H/18.1/185

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

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