APPROVED PACKAGE INSERT

SCHEDULING STATUS

S3

PROPRIETARY NAME (and dosage form)

AUSTELL–FUROSEMIDE 20 mg TABLETS

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COMPOSITION

AUSTELL-FUROSEMIDE 20 mg TABLETS:

Each tablet contains furosemide 20 mg.

AUSTELL-FUROSEMIDE 40 mg TABLETS:

Each tablet contains furosemide 40 mg.

PHARMACOLOGICAL CLASSIFICATION

A18.1. Diuretics.

PHARMACOLOGICAL ACTION

Furosemide inhibits the reabsorption of sodium and water predominantly in the ascending loop of Henle but also in the proximal tubule.

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

INDICATIONS

- **AUSTELL-FUROSEMIDE** is used as an adjunct in the treatment of acute pulmonary oedema.
- Cardiac oedema in conjunction with other cardiac therapy.
- **AUSTELL-FUROSEMIDE** is used for the treatment of mild to moderate hypertension.
- Renal oedema in nephrotic syndrome.
- It is indicated in the treatment of cerebral oedema.
- Ascites due to liver cirrhosis, mechanical obstruction or cardiac failure.
- Forced diuresis in the management of hypercalcaemia and certain poisoning e.g. barbiturates.
- In burns: to reduce local oedema and to prevent oliguria from progressing to complete anuria.

CONTRA-INDICATIONS

Patients who are hypersensitive to furosemide or sulphonamides. **AUSTELL-FUROSEMIDE** is contra-indicated if increasing azotaemia and oliguria occur during treatment of severe progressive renal disease, anuria, hypokalaemia, hyponatraemia, hypovolaemia with or without hypotension. In hepatic coma and in states of electrolyte depletion, therapy with **AUSTELL-FUROSEMIDE** should not be instituted until the basic condition is corrected or improved.

Furosemide should not be given to lactating women. Furosemide should be administered during pregnancy only if strictly indicated, and then only for short periods of time (see PREGNANCY AND LACTATION).

WARNINGS

Electrolyte balance of the patients receiving **AUSTELL-FUROSEMIDE** must be monitored particularly in the elderly, diabetics and patients with cardiac, hepatic or renal impairment. Careful monitoring is required in patients with hypotension.

INTERACTIONS

When a cardiac glycoside is administered concurrently it should be remembered that potassium deficiency increases the sensitivity of myocardium to digitalis. In case of glucocorticoid medication or abuse of laxatives the risk of increased potassium loss has to be borne in mind.

AUSTELL-FUROSEMIDE may potentiate the nephrotoxic effects of certain antibiotics (e.g. aminoglycosides). Therefore **AUSTELL-FUROSEMIDE** should be used with caution in patients with antibiotic induced renal impairment. The ototoxicity of aminoglycoside antibiotics (e.g. kanamycin, gentamycin, tobramycin) may be potentiated when **AUSTELL-FUROSEMIDE** is used concurrently. The hearing defects that result may be irreversible. Therefore, this drug combination should be restricted to vital indications.

Sometimes **AUSTELL-FUROSEMIDE** may diminish the potency of other medicines (e.g the effect of anti-diabetics and pressor amines) or potentiates their effects

(e.g in case of salicylates , theophylline, lithium, and curaremimetic muscle relaxants)

The action of other hypotensive medicines may be potentiated by **AUSTELL-FUROSEMIDE**. Especially in combination with ACE-inhibitors, a marked fall in blood pressure may be seen.

Non-steroidal anti-inflammatory agents (e.g. Indomethacin, acetylsalicylic acid) may antagonise the action of **AUSTELL-FUROSEMIDE** and may cause renal failure in case of pre-existing hypovolaemia.

Concurrent administration of **AUSTELL-FUROSEMIDE** and sucralfate should be avoided as sucralfate reduces the absorption of **AUSTELL-FUROSEMIDE** and hence weakens its effect.

PREGNANCY AND LACTATION

Furosemide should not be given to lactating women. Furosemide should be administered during pregnancy only if strictly indicated, and then only for short periods of time (see CONTRA-INDICATIONS).

DOSAGE AND DIRECTIONS FOR USE

Adults:

The usual dose of Furosemide is 20 mg to 80 mg given as a single dose preferably in the morning.

In the treatment of oedema, the usual initial dose is 40 mg once daily by mouth, adjusted as necessary according to response. Mild cases may respond to 20 mg daily or 40 mg on alternate days. Some patients may require doses of 80 mg or more daily given as one or two doses daily or intermittently. Severe cases may require gradual titration of furosemide dosage up to 600 mg daily.

In the treatment of hypertension, furosemide is given in doses of 40 to 80 mg daily by mouth.

In the treatment of Forced Diuresis (e.g. management of barbiturate poisoning) 20–40 mg furosemide is given in addition to infusion of electrolyte solution. Further

treatment depends on the elimination of urine and must include substitution of the fluid and electrolyte losses.

In poisoning with acid or basic substances the elimination rate can further be increased by alkalisation or acidification of the urine, respectively.

Children:

The usual dose by mouth is 1 to 3 mg per kg- body weight daily up to a maximum of 40 mg daily.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS

Side-effects:

Haematological disorders

Less frequent: Haemolytic anaemia, leucopoenia and thrombocytopenia (with purpura), and agranulocytosis. Other side effects include transient increase in serum creatinine and urea, increase in serum cholesterol and triglycerides.

Electrolyte imbalances

Less frequent: Fluid and electrolyte disturbances such as hypokalaemia may occur, especially in cases of low potassium diet, vomiting or chronic diarrhoea. Because of the strong natriuretic effect of **AUSTELL-FUROSEMIDE**, it may produce hyponatraemia (weakness, dizziness, lethargy, calf muscle cramps, anorexia, vomiting and/or mental confusion).

Excessive diuresis may result in blood coagulation disorders, particularly in the elderly patients.

Endocrine disorders

Less frequent: Acute pancreatitis. Alterations in glucose tolerance tests with abnormalities of the fasting and 2 hour post-prandial sugar have been observed, and cases of precipitation of diabetes mellitus have been reported.

Nervous system disorders

Less frequent: **AUSTELL-FUROSEMIDE** may lower the serum calcium levels and cases of tetany have been reported.

Eye disorders

Less frequent: Blurring of vision.

Ear disorders

Less frequent: Tinnitus and deafness may occur in patients with renal insufficiency.

Vascular disorders

Less frequent: Postural hypotension. Excessive diuresis may result in circulatory disturbances, such as a feeling of pressure in the head, vertigo or visual impairment; in extreme cases hypovolaemia, dehydration, dryness of mouth, and circulatory collapse may also occur, particularly in the elderly patients. However, with individualised dosage, acute haemodynamic reactions are generally not to be expected, although diuresis sets in rapidly.

Gastro-intestinal disorders

Less frequent: Nausea, vomiting or diarrhoea.

Skin and subcutaneous tissue disorders

Less frequent: Dermatitis including urticaria, exfoliative dermatitis, photosensitivity, pruritus, vesicular cutaneous eruptions, paraesthesia, vasculitis and rash.

Metabolic disorders

Less frequent: Gout as a result of hyperuricaemia.

Renal disorders

Symptoms of obstructed micturition (e.g. in hydronephrosis, prostatic hypertrophy, uretherostenosis) may become manifest or aggravated under the action of diuretics.

Special precautions:

Renal disorders

It should be used with care in patients with prostatic hyperplasia or impairment of micturition since it can precipitate acute urinary retention.

Electrolyte imbalances

Although administration of Furosemide only rarely leads to hypokalaemia, a potassium rich diet is advisable. Treatment with potassium containing or potassium sparing preparations may be indicated.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

After ingestion of an overdose there is some danger of dehydration and electrolyte depletion due to excessive diuresis. The guiding principle of treatment is water and electrolyte replacement in accordance with urine output (with monitoring of carbohydrate metabolism if necessary). If difficulty in micturition is proved or

suspected, as in case of prostatic hypertrophy or impairment of consciousness, care must be taken to ensure a free outflow of urine from the bladder.

IDENTIFICATION

AUSTELL–FUROSEMIDE 20 mg:

White or off white, circular tablets, marked with ‘F & 20’ on one side and ‘BL’ embossing on other side.

AUSTELL–FUROSEMIDE 40 mg:

White or off white, circular tablets, with a breakline which divides ‘F & 40’ on one side and ‘BL’ embossing on other side.

PRESENTATION

AUSTELL–FUROSEMIDE 20 mg:

Blister packs (Opaque PVC coated PVDC film and Aluminium foil) of 2 x 14, 3 x 10, 4 x 14 and 6 x 14 tablets.

Securipack (White HDPE jars) of 250, 500 and 1000 tablets.

AUSTELL–FUROSEMIDE 40 mg:

Blister packs (Opaque PVC coated PVDC film and Aluminium foil) of 2 x 14, 3 x 10, 4 x 14, 6 x 14 and 8 x 14 tablets.

Securipack (White HDPE jars) of 250, 500 and 1000 tablets.

STORAGE INSTRUCTIONS

Store in a dry place at or below 25 °C. Protect from light.

Keep the securipack tightly closed.

Keep blister packs in carton until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

AUSTELL-FUROSEMIDE 20 mg: 37/18.1/0432

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

Austell Laboratories (Pty) Ltd.

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DATE OF PUBLICATION OF THIS PACKAGE INSERT

23 September 2005