Approved Patient Information Leaflet for Medicines for Human:

Read all of this leaflet carefully before you start using this medicine

- Keep this leaflet. You may need to read it again.
- **I**f you have any further questions, please ask your doctor or your pharmacist.

This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

AUSTELL FUROSEMIDE 20 mg TABLETS

AUSTELL FUROSEMIDE 40 mg TABLETS

WHAT AUSTEL FUROSEMIDE CONTAINS

AUSTELL FUROSEMIDE 20 mg:

Each tablet contains furosemide 20 mg**.**

AUSTELL FUROSEMIDE 40 mg:

Each tablet contains furosemide 40 mg.

The inactive ingredients are: Lactose monohydrate, magnesium stearate, maize starch, pregelatinised starch and sodium starch glycollate.

WHAT AUSTELL FUROSEMIDE IS USED FOR

AUSTELL FUROSEMIDE is a diuretic (medicine that forces your body to urinate) and is used in the treatment of:

- Abnormal build up of fluids (oedema) in cellular tissue or body cavities due to liver diseases, heart diseases, kidney diseases, mechanical obstruction or pregnancy.

- Burns: to reduce local build up of fluids (oedema) and to prevent decreased urination.
- High blood pressure of mild to moderate degree.
- To force urination when you have too high levels of calcium in your blood.
- To force urination in the case of certain poisoning e.g. barbiturates.

Take special care with AUSTELL FUROSEMIDE:

Tell your doctor if:

- If you suffer from liver diseases. You may be more prone to potassium deficiency. A potassium-rich diet (lean meat, potatoes, bananas, tomatoes, cauliflower, spinach, dried fruit etc) is always advisable.
- If you use heart medication called cardiac glycosides.
- If you use cephalosporin antibiotics. **AUSTELL FUROSEMIDE** may aggravate the kidney toxicity caused by these antibiotics.

Pregnancy and breast-feeding:

If you are pregnant or breast feeding your baby while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice. The safety of **AUSTELL FUROSEMIDE** has not yet been established in pregnant women and breast-feeding mothers

Driving and using machinery:

Your ability to cope with road traffic or to operate machinery may be impaired, especially at the beginning of **AUSTELL FUROSEMIDE** treatment or when you consume alcohol during **AUSTELL FUROSEMIDE** therapy.

Using other medicines with AUSTELL FUROSEMIDE:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **AUSTELL FUROSEMIDE** with these medicines may cause undesirable interactions. Tell your doctor or pharmacist if you are taking any other medicines, including any you have bought at your pharmacy, supermarket or health food shop. Please consult your doctor, pharmacist or other healthcare professional for advice.

Tell you doctor if you are using:

- Medication for your heart, especially digitalis.
- Laxatives.
- Medicines for inflammation e.g. glucocorticoid medication, indomethacine and aspirin.
- Antibiotics called amino-glycosides (e.g. kanamycin, gentamicin, tobramycin); **AUSTELL FUROSEMIDE** may worsen the kidney or ear toxicity caused by these antibiotics.
- Cisplatin (medicine used for cancer treatment) together with parenteral **AUSTELL FUROSEMIDE** may induce hearing defects.
- Anti-diabetic medicines. Co-administration of **AUSTELL FUROSEMIDE** may cause these medicines to be less effective.
- Theophylline (asthma medication), lithium (treatment for mood swings), certain muscle relaxants and high blood pressure medication. Co-administration of **AUSTELL FUROSEMIDE** may increase the effect of these medicines.
- Sucralfate (for treatment of stomach ulcer). Sucralfate reduce the effect of **AUSTELL FUROSEMIDE.**

Children:

The dosage is 1 to 3 mg per kg of body weight of the child daily up to a maximum of 40 mg daily.

Special care must be taken when giving **AUSTELL FUROSEMIDE** to children.

In the event of over dosage consult your doctor or pharmacist.

POSSIBLE SIDE EFFECTS

Not all side effects have been reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Contact your doctor if you experience the following:

- Allergic reactions (skin rash, itchy skin).
- Unusual weakness or tiredness, dizziness, calf muscle cramps, anorexia, severe stomach pain with nausea, vomiting and diarrhoea (running stomach).
- Fever or chills, lower back or side pains, painful or difficult urination, cough, unusual bleeding or bruising.
- Gout.
- Ringing or buzzing in the ears, or any loss of hearing.

Some patients may experience the following side effects. Contact your doctor if these effects continue or are bothersome:

- Blurred vision, headache, diarrhoea, increased sensitivity of skin to sunlight, confusion.
- Dizziness or light-headedness when getting up from a lying or sitting position.
- Gout.

STORING AND DISPOSING INFORMATION

Keep this medicine in a dry place at or below 25 ºC. Protect from light.

Keep blister packs in carton until required for use. Do not transfer the medicine to any other container.

Keep the securipack tightly closed.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

DO NOT USE AFTER THE DATE WHICH IS STAMPED ON THE PACK.

PRESENTATION OF AUSTELL FUROSEMIDE

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 or 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 or 1000 tablets.

IDENTIFICATION OF AUSTELL FUROSEMIDE

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.

REGISTRATION NUMBER/REFERENCE NUMBER

AUSTELL FUROSEMIDE 20 mg: 37/18.1/0432

AUSTELL FUROSEMIDE 40 mg: 37/18.1/0433

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