Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Diumide-K Continus prolonged release, film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Furosemide 40 mg
Potassium Chloride 600 mg (prolonged release).

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Prolonged release, film-coated tablets.

Orange/white, film coated, bi-layered tablets with the letters ‘DK’ on the orange coloured layer.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the management of fluid retention in which potassium supplementation is required in support of a diuretic administered daily, in mild to moderate hypertension, and in oedema of various aetiologies.

4.2 Posology and method of adminstration

Route of Administration

Oral.

Adults only

The usual dosage is one tablet daily.

4.3 Contraindications

1. Use of the combination in the presence of hyperkalaemia, precoma associated with hepatic cirrhosis, or Addison’s disease.

2. Use in children.

3. Hypersensitivity to furosemide, potassium chloride or any other constituent of the tablets.

4. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.4 Special warnings and special precautions for use

1. Patients who are being treated with this preparation require regular supervision with monitoring of fluid and electrolyte state to avoid inadequate potassium supplementation or excessive loss of fluid.

2. The dosage of potassium supplied with this regimen is not adjusted to the requirements of any patients and the physician must ensure continued suitability of dosage for each patient particularly if he is on long-term treatment.

3. Potassium chloride may produce oesophageal and small bowel ulceration in some patients particularly if they are on long-term treatment. There is evidence to suggest that patients with systemic cardiovascular disease or local disorders of gastrointestinal motility are particularly at risk.

4. The preparation should only be used with particular caution in elderly patients, or those with potential obstruction of the urinary tract, or with disorders rendering their electrolyte balance precarious or those with renal insufficiency.

5. Furosemide may induce hyperglycaemia particularly in patients with latent diabetes, and may necessitate adjustment of control by hypoglycaemic agents in cases of diabetes mellitus.

6. Hyperuricaemia and gout, may be induced by furosemide.

7. Ototoxicity may occur.

8. FD+C Yellow (E110) can cause allergic-type reactions such as asthma. This is more common in people who are allergic to aspirin.

4.5 Interaction with other medicinal products and other forms of interaction

1. The concomitant administration of this preparation with cardiac glycosides or hypotensive agents may necessitate adjustment of the dosage of those drugs.

2. Furosemide may aggravate the nephrotoxicity of cephaloridine. Furosemide may potentiate the nephrotoxicity and ototoxicity of aminoglycosides.

3. Concurrent use with lithium may lead to increased serum lithium levels requiring adjustment of dosage.

4.6 Pregnancy and lactation

Animal studies did not show a teratogenic effect. There have been no adequate studies in human beings. The preparation should only be used during pregnancy or lactation if considered essential by the physician. The drug/metabolite is excreted in breast milk.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Side effects include gastrointestinal disturbances, hypotension, rash, photosensitivity, allergic reactions, blood dyscrasias and pancreatitis have been reported.

4.9 Overdose

Overdosage is characterised by excessive diuresis. Replace fluids and correct electrolyte imbalance.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

DIUMIDE-K CONTINUS tablets contain the diuretic furosemide and potassium chloride. Furosemide is a loop diuretic, inhibiting resorption from the ascending Loop of Henle. It is used for the treatment of oedematous states of various aetiologies. Potassium chloride is present in the tablets to counteract the urinary loss of potassium.

5.2 Pharmacokinetic properties

The furosemide layer has normal release characteristics. Furosemide produces a diuresis within one hour and it is complete within six hours. Furosemide has a biphasic half life in the plasma with a terminal elimination phase of up to about 1½ hours. The potassium chloride in DIUMIDE-K CONTINUS tablets is incorporated in the modified release system. This ensures a prolonged release giving maximum absorption, and avoiding 'flushing out' of the potassium by the action of the diuretic.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydroxyethyl Cellulose
Gelatin
Cetostearyl Alcohol
Talc
Magnesium Stearate
FD&C Yellow (E110)
Lactose Monohydrate
Povidone
Pregelatinised Maize Starch

Film coat

Hypromellose
Macrogol 400

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

Three years

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

PVC/PVdC blister with aluminium foil backing containing 30 tablets.

6.6 Instructions for use and handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 913/4/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4th January 1978

Date of last renewal: 4th January 2003

10 DATE OF REVISION OF THE TEXT

July 2004