

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Frusid Tablets
Furosemide 40 mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Furosemide BP 40.00 mg

3 PHARMACEUTICAL FORM

Tablets

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Frusid is indicated for the treatment of oedema associated with congestive heart failure, cirrhosis of the liver and renal disease, including the nephrotic syndrome. Frusid may be used in the treatment of mild or moderate hypertension either alone or in combination with other anti-hypertensive drugs. In oedema resulting from damage to vessel walls or as a result of mechanical obstruction. Ascites.

4.2 Posology and method of administration

Adults:

Dosage will vary from 1-3 tablets daily or on alternate days. The usual initial dose is 1 tablet (40 mg) daily which should be adjusted to achieve the effective dose. In mild oedema 1 tablet on alternate days or on three consecutive days of the week is recommended. In patients with resistant oedema daily doses of 2 or 3 tablets may be required.

Children:

The dosage range is from 1 to 3 mg/kg of bodyweight daily.

Elderly:

Dosage should be titrated until the required response is achieved, because in the elderly Furosemide is generally eliminated more slowly.

Method of administration: Oral

4.3 Contraindications

Frusid is contraindicated in anuria, renal failure, electrolyte deficiency and pre-comatose states associated with liver cirrhosis. Hypersensitivity to sulphonamides.

4.4 Special warnings and precautions for use

Warnings:

There is an increased risk of developing acute retention in patients with prostatic hypertrophy. It may be necessary to adjust the dosage of cardiac or anti-hypertensive agents which are taken concurrently. It will be necessary to correct hypotension or hypovolaemia before commencing treatment.

Concomitant administration of Furosemide may increase the toxic effects of nephrotoxic antibiotics.

The insulin requirements of diabetic patients may increase. Latent diabetics may become manifest.

May cause hypokalaemia and hyponatraemia. May aggravate gout.

Precautions:

Observe caution in patients with a history of electrolyte deficiency, liver failure, prostatic enlargement and porphyria.

4.5 Interaction with other medicinal products and other forms of interaction

Certain non-steroidal anti-inflammatory agents antagonise the action of Frusid and may cause renal failure in cases of pre-existing hypovolaemia. Frusid may attenuate the effects of other drugs, for example antidiabetics and pressor

amines. Frusid may occasionally potentiate the effects of drugs such as salicylates and curare-type muscle relaxants.

Interactions may occur with ototoxic antibiotics. Sodium retention and increased potassium loss may be caused by glucocorticoids.

Serum lithium levels may be increased during concomitant treatment necessitating adjustment of the lithium dosage.

Increased toxicity may result if cardiac glycosides are administered.

Profound diuresis is possible if metolazone is given with Furosemide.

4.6 Pregnancy and lactation

Furosemide should only be used in pregnancy if strictly indicated and then only for short-term treatment.

Furosemide should be used with caution in nursing mothers as the drug may inhibit lactation.

4.7 Effects on ability to drive and use machines

The ability to drive and to use machines may be affected due to reduced mental alertness.

4.8 Undesirable effects

Side effects such as nausea, malaise and gastric upset occasionally occur but do not require cessation of treatment.

Calcium depletion, hyponatraemia, hypokalaemia and hypomagnesaemia may occur.

In commencing with other diuretics a transient rise in creatinine and urea levels have been reported. As with other sulphonamide-based diuretics, hyperuricaemia may occur and, in rare cases, clinical gout may be precipitated.

Although the incidence of allergic reactions, e.g. skin rashes, are infrequent, treatment should be withdrawn when these occur.

Aggravation of metabolic acidosis may occur.

As a rare complication bone marrow depression has been reported and may necessitate withdrawal of treatment.

Other adverse effects include: hypochloreaemic alkalosis, hypotension, temporary increase in plasma cholesterol and triglyceride concentrations and photosensitivity.

Tinnitus and deafness may occur but usually with large parenteral doses and rapid administration and in renal impairment.

4.9 Overdose

Because of the danger of dehydration and electrolyte depletion resulting from excessive diuresis, treatment should be aimed at fluid replacement and correction of the electrolyte imbalance.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Furosemide is insoluble in water and chloroform. It is soluble in 1 in 75 of alcohol, 1 in 850 of ether and 1 in 15 of acetone.

Its effects are reached within one hour of an oral dose and lasts from 4 to 6 hours.

5.2 Pharmacokinetic properties

Furosemide is rapidly absorbed from the gastro-intestinal tract. It has a biphasic half-life in the plasma with a terminal elimination phase range up to 1½ hours. It is 99% bound to plasma proteins and is mainly excreted in the urine unchanged, but also in the form of glucuronide and free anine metabolites. Variable amounts are also excreted in the bowel. Furosemide crosses the placental barrier and is excreted in milk.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Maize starch
Potato starch
Colloidal silicon dioxide aerosil 200/Cabosil M5
Magnesium stearate

6.2 Incompatibilities

None known.

6.3 Shelf life

48 months for containers, 24 months for blister packs.

6.4 Special precautions for storage

Store below 25°C in a dry place.

6.5 Nature and contents of container

High density polystyrene with polythene lids and/or polypropylene containers with polypropylene or polythene lids and polyurethane foam sponge wads.
Pack sizes: 28, 30, 56, 60, 84, 100, 500 and 1000 tablets.

PVC/Aluminium blister-packs.
Pack sizes: 28, 30, 56, 60, 84, 100, 500 and 1000 tablets.

6.6 Special precautions for disposal

No special instructions

7 MARKETING AUTHORISATION HOLDER

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PL 33414/0047

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