

PRODUCT NAME: FUROSEMIDE INJECTION BP 10MG/ML, 5ML
Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

Furosemide Injection BP 50mg/5ml.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1ml of sterile solution for injection contains Furosemide 10mg.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear, colourless or almost colourless solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

As a diuretic in the treatment of cardiac, pulmonary, hepatic and renal oedema, where a prompt and effective diuresis is required.

4.2 Posology and method of administration

Adults

The usual initial dose in adults is 20 to 50mg, administered by intramuscular injection or by slow intravenous injection at a rate not exceeding 4mg/minute. A second dose may be given not less than 2 hours later, according to the patient's response.

Elderly

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

Children

For children, the suggested dose is 0.5 to 1.5mg/kg body weight daily to a maximum total daily dose of 20mg.

4.3 Contra-indications

Hypokalaemia, pre-coma associated with hepatic cirrhosis, Addison's disease. Anuria. Hypersensitivity to furosemide or sulphonamides.

4.4 Special warnings and precautions for use

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

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Particular care is required when treating elderly patients, or those with potential obstruction of the urinary tract, or with disorders rendering their electrolyte balance precarious.

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

Infusion rates in excess of 4mg/minute are associated with an increased risk of ototoxicity, usually reversible hearing loss.

Bone marrow depression has been reported as a rare complication and necessitates withdrawal of treatment. The haemopoietic state should, therefore, be monitored regularly during use.

Use with caution in patients with hypotension, liver failure, prostate enlargement & porphyria.

4.5 Interactions with other medicaments and other forms of interaction

The concomitant administration of this preparation with cardiac glycosides, hypotensive agents or non-depolarising muscle relaxants, may necessitate adjustment of the dosage of those drugs.

Furosemide may aggravate the nephrotoxicity of cephaloridine and the aminoglycosides. Concurrent use of furosemide with aminoglycosides may increase the potential for ototoxicity.

The action of furosemide may be inhibited by concomitantly administered non-steroidal anti-inflammatory agents.

Although loop diuretics such as furosemide seem less likely to cause lithium retention than do thiazide diuretics, caution is required when administering furosemide concomitantly with lithium.

Corticosteroids, corticotrophin and amphotericin B also cause potassium loss and severe potassium depletion may occur when administered concurrently with furosemide.

Concurrent use of Furosemide and phenytoin can reduce the diuretic effect of the former.

Potassium depletion that can result from furosemide administration may potentiate digitalis toxicity and can disturb the action of some antiarrhythmic drugs.

Probenecid may reduce the renal clearance of Furosemide.

4.6 Pregnancy and lactation

Furosemide crosses the placenta and is excreted in breast milk. There is no evidence of a teratogenic effect in animal studies. Experience of use in human pregnancy does not to date suggest evidence of teratogenesis. However, furosemide should only be used in pregnancy if considered essential by the physician and should be avoided in women who are nursing infants.

4.7 Effects on ability to drive and use machines

No known effects on ability to drive and use machines.

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4.8 Undesirable effects

Ear and labyrinth disorders

Inner ear signs and symptoms: Tinnitus
Hearing losses: deafness.

Gastrointestinal disorders

Diarrhoea (excl infective): Diarrhoea.
Acute and chronic pancreatitis: pancreatitis.

Hepatobiliary disorders

Hepatocellular damage: Liver damage

Investigations

Blood cholesterol increased: Plasma cholesterol increased
Blood triglycerides increased: Plasma triglycerides increased

Metabolism and nutrition disorders

Magnesium metabolism disorders: Hypomagnesaemia
Calcium metabolism disorders: Hypocalcaemia
Alkalosis hypochloraemic : Hypochloraemic alkalosis
Purine metabolism disorders NEC: Hyperuricaemia, Gout
Total Fluid Volume Decreased: Dehydration
Potassium imbalance: hypokalaemia
Sodium imbalance: hyponatraemia
Electrolyte imbalance.

Musculoskeletal and connective tissue disorders

Muscle spasms: Muscle cramps

Nervous System Disorders:

Peripheral Neuropathies: Neuropathy.

Renal and Urinary Disorders:

Nephropathies: Nephritis

Skin and subcutaneous tissue disorders

Epidermal and dermal conditions: Rash, Photosensitivity

Vascular Disorders:

Vascular hypotension disorders: hypotension.

4.9 Overdosage

In overdosage, excessive diuresis may lead to hypotension, dehydration and electrolyte depletion. If overdosage occurs, treatment should be directed to correcting dehydration and electrolyte depletion.

5. **PHARMACOLOGICAL PROPERTIES**

5.1 Pharmacodynamic properties

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Furosemide is a potent diuretic which acts primarily by inhibiting electrolyte absorption in the loop of Henle.

5.2 Pharmacokinetic properties

Following intravenous administration, diuresis occurs within 5 minutes, reaches a maximum within 20 – 60 minutes and persists for approximately 2 hours. Furosemide is strongly bound to plasma proteins and is excreted mostly unchanged through the kidneys. The main site of action is the ascending limb of the loop of Henle.

5.3 Preclinical safety data

No further information other than that which is contained in other sections of the Summary of Product Characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Chloride
Sodium Hydroxide
Water for Injections

6.2 Incompatibilities

Furosemide Injection BP 50mg/5ml should not be mixed with any other preparations.

6.3 Shelf life

Unopened: 3 years.
The product should be used immediately after opening.

6.4 Special precautions for storage

Do not store above 25°C.
Keep the ampoules in the outer carton.
Do not refrigerate or freeze.

6.5 Nature and contents of container

5ml, amber glass ampoules, glass type 1 Ph Eur borosilicate glass, packed in cardboard cartons to contain 10 x 5ml ampoules.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from

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such medicinal product and other handling of the product.

For single use only. If only part used, discard the remaining solution.

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7. MARKETING AUTHORIZATION HOLDER

Antigen Pharmaceuticals Ltd.,
Roscrea,
County Tipperary,
Ireland.

8. MARKETING AUTHORIZATION NUMBER

PA 73/59/5

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF AUTHORIZATION

28th May, 1990 / 28th March 2005

10. DATE OF (PARTIAL) REVISION OF THE TEXT

February 2008