1.7	**Product information**
1.7.1	**Summary of Product characteristics**

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

FUROSEMIDE INJECTION BP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition:

Each ml contains:

Furosemide BP 10 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

When a prompt diuresis is required. Use in emergencies or when oral therapy is precluded. Indications include:- Oedema and/or ascites caused by cardiac or hepatic diseases

- Oedema caused by renal diseases (in case of nephrotic syndrome, treatment of the underlying disease isessential)- Pulmonary oedema (e.g. in case of acute heart failure)

- Hypertensive crisis (in addition to other therapeutic measures)

4.2 Posology And Method of Administration

Route of administration: intravenous or (in exceptional cases) intramuscular

General: The parenteral administration of furosemide is indicated in cases where oral administration is not feasible or not efficient (for example in case of reduced intestinal absorption) or when a quick effect is required. To achieve optimum efficacy and suppress counter-regulation, a continuous furosemide infusion is generally to be preferred to repeated bolus injections. Consideration should be given to current clinical guidelines where available. Where continuous furosemide infusion is not feasible for follow-up treatment after one or several acute bolus doses, a follow-up regimen with low doses given at short intervals (approx. 4 hours) is to be preferred to a regimen with higher bolus doses at longer

intervals.

Therapy should be individualized according to patient response to gain maximal therapeutic response and to determine the minimal dose needed to maintain that response.

Intravenous furosemide must be injected or infused slowly; a rate of 4 mg per minute must not be exceeded and should never be given in association with other medicinal products in the same syringe.

Generally, Furosemide should be administered intravenously. Intramuscular administration must be restricted to exceptional cases where neither oral nor intravenous administration is feasible. It must be noted that intramuscular injection is not suitable for the treatment of acute conditions such as pulmonary oedema.

Adults:

In the absence of conditions requiring a reduced dose (see below) the initial dose recommended for adults and adolescents over 15 years, is of 20 mg to 40 mg furosemide by intravenous (or in exceptional cases intramuscular) administration; the maximum dose varying according to individual response.

If larger doses are required, they should be given increasing by 20 mg increments and not given more often than every two hours.

In adults, the recommended maximum daily dose of furosemide administration is 1500 mg.

When administered as an infusion, Furosemide may be administered undiluted using a constant-rate infusion pump, or the solution may be further diluted with a compatible carrier fluid, such as Sodium Chloride Injection B.P. or Ringer's Solution for Injection. In either case, the rate of infusion should not exceed 4mg/minute. The parenteral administration of furosemide is indicated in cases where oral administration is not feasible or not efficient (for example in case of reduced intestinal absorption) or when a quick effect is required. In cases where parenteral administration is used, the switch to oral administration is recommended, as soon as possible.

Children and adolescents (up to 18 years of age):

The experience in children and adolescents are limited. The intravenous administration of furosemide to children and adolescents below 15 years is only recommended in exceptional cases.

The dosage will be adapted to the body weight, and the recommended dose ranges from 0.5 to 1 mg/kg body weight daily up to a maximum total daily dose of 20 mg.

There should be a switch to oral therapy as soon as possible.

Renal impairment:

In patients with severe impairment of renal function (serum creatinine > 5 mg/dl) it is recommended that an infusion rate of 2.5 mg furosemide per minute is not exceeded.

Elderly:

The recommended initial dose is 20 mg/day, increasing gradually until the required response is achieved.

Special dosage recommendations:

For adults, the dose is based on the following conditions:

- Oedema associated to chronic and acute congestive heart failure

The recommended initial dose is 20 to 40 mg daily. This dose can be adapted to the patient´s response, as necessary. The dose should be given in two or three individual doses per day for chronic congestive heart failure and as a bolus for acute congestive heart failure.

- Oedema associated with renal disease

The recommended initial dose is 20 to 40 mg daily. This dose can be adapted to the response as necessary. The total daily dose can be administered as a single dose or as several doses throughout the day. If this does not lead to an optimal fluid excretion increase, furosemide must be administered in continuous intravenous infusion, with an initial rate of 50 mg to 100 mg per hour.

Before beginning the administration of furosemide, hypovolaemia, hypotension and acid-base and electrolytic imbalances must be corrected.

In dialyzed patients, the usual maintenance dose ranges from 250 mg to 1,500 mg daily.

In patients with nephrotic syndrome the dosage must be determined with caution, because of the risk of a higher incidence of adverse events.

- Oedema associated with hepatic disease

When intravenous treatment is absolutely needed, the initial dose should range from 20 mg to 40 mg. This dose can be adapted to the response as necessary. The total daily dose can be administered as a single dose or in several doses.

Furosemide can be used in combination with aldosterone antagonists in cases in which these agents in monotherapy are not sufficient. In order to avoid complications such as orthostatic intolerance or acid-

base and electrolytic imbalances or hepatic encephalopathy, the dose must be carefully adjusted to achieve a gradual fluid loss. The dose may produce in adults a daily body weight loss of approximately 0.5 kg. In cases of ascites with oedema, weight loss induced by enhanced diuresis should not exceed 1 kg / day.

- Pulmonary oedema (in acute heart failure)

The initial dose to be administered is 40 mg furosemide by intravenous application. If required by the condition of the patient, another injection of 20 to 40 mg furosemide is given after 30 – 60 minutes.

Furosemide should be used in addition to other therapeutic measures.

- Hypertensive crisis (in addition to other therapeutic measures)

The recommended initial dose in hypertensive crisis is 20 mg to 40 mg administrated in bolus by intravenous injection. This dose can be adapted to the response as necessary.

4.3 Contraindications:

- Hypersensitivity to the active substance or to any of the excipients.

– Patients with anuria or renal failure with oligoanuria not responding to furosemide

– Renal failure as a result of poisoning by nephrotoxic or hepatotoxic agents

– Renal failure associated with hepatic coma

– Patients with severe hypokalaemia or severe hyponatraemia

– Patients with hypovolaemia (with or without hypotension) or dehydration

– Patients in pre-comatose and comatose state associated with hepatic encephalopathy

– Patients with hypersensitivity to sulphonamides (e.g. Sulfonyureas or antibiotics of sulphonamides group) may show cross-sensitivity to furosemide

– Lactation (see section 4.6)

4.4 Special Warnings And Precautions For Use

Careful monitoring is required in case of:

- Patients with partial obstruction of urinary outflow (e.g. prostatic hypertrophy, hydronephrosis, ureterostenosis).

Urinary output must be secured

- Patients with hypotension or at increased risk from pronounced fall in blood pressure (patients with coronary artery stenosis or cerebral artery stenosis)
- Patients with manifest or latent diabetes mellitus or variation of glycaemia (regular monitoring of blood glucose levels necessary)
- Patients with gout and hyperuricaemia (regular monitoring of uric acid levels in serum necessary)
- Patients with hepatic disease or hepatorenal syndrome (renal impairment associated to severe hepatic disease)
- Hypoproteinaemia (associated to nephrotic syndrome, furosemide´s effect may be reduced and its ototoxicity increased)
- Co-administration with lithium salts (monitoring of lithium levels is required, see section 4.5)
- Acute porphyria (the use of diuretics is considered to be unsafe in acute porphyria and caution should be exercised)
- In cases of ascites with oedema, weight loss induced by enhanced diuresis should not exceed 1 kg / day

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- Too vigorous diuresis may cause orthostatic hypotension or acute hypotensive episodes.
- NSAIDs may antagonise the diuretic effect of furosemide and other diuretics. Use of NSAIDs with diuretics may increase the risk of nephrotoxicity.
- Where indicated, steps should be taken to correct hypotension or hypovolaemia before commencing therapy.

Cautious dose titration is required:

- Electrolyte variations (e.g. hypokalaemia, hyponatraemia). Potassium supplements and/or dietary measures may be needed to control or avoid hypokalemia
- Fluid variations, dehydration, blood volume reduction with circulatory collapse and possibility of thrombosis and embolism, particular in elderly, with excessive use
- Ototoxicity (if administered faster than 4 mg/min - other ototoxic compounds administered concomitantly can increase this risk, see section 4.5
- Administration of high dosages
- Administration in progressive and severe renal disease

- Administration with sorbitol. Concomitant administration of both substances may lead to increased dehydratation (sorbitol might cause additional fluid loss by inducing diarrhoea)
- Administration in Lupus Erythematosus
- Medication that prolong the QT interval

Symptomatic hypotension leading to dizziness, fainting or loss of consciousness can occur in patients treated with furosemide, particularly in the elderly, patients on other medications which can cause hypotension and patients with other medical conditions that are risks for hypotension.

Premature infants (possible development of nephrocalcinosis /nephrolithiasis; renal function must be monitored and renal ultrasonography performed). In premature infants with respiratory distress syndrome, diuretic treatment with furosemide during the first weeks of life can increase the risk of persistent ductus arteriosus Botalli.

Caution should be observed in patients liable to electrolyte deficiency.

Regular monitoring of serum sodium, potassium and creatinine is generally recommended during furosemide therapy; particularly close monitoring is required in patients at high risk of developing electrolyte imbalances or in case of significant additional fluid loss. (e.g. due to vomiting or diarrhoea).

Hypovolaemia or dehydration as well as any significant electrolyte and acid-base disturbances must be corrected.

This may require temporary discontinuation of furosemide.

In patients who are at high risk for radiocontrast nephropathy, furosemide is not recommended to be used for diuresis as part of the preventative measures against radiocontrast-induced nephropathy.

Concomitant use with risperidone

In risperidone placebo-controlled trials in elderly patients with dementia, a higher incidence of mortality was observed in patients treated with furosemide plus risperidone (7.3%; mean age 89 years, range 75-97 years) when compared to patients treated with risperidone alone (3.1%; mean age 84 years, range 70-96 years) or furosemide alone (4.1%; mean age 80 years, range 67-90 years). Concomitant use of risperidone with other diuretics (mainly thiazide diuretics used in low dose) was not associated with similar findings.

No pathophysiological mechanism has been identified to explain this finding, and no consistent pattern

for cause of death observed. Nevertheless, caution should be exercised and the risks and benefits of this combination or cotreatment with other potent diuretics should be considered prior to the decision to use. There was no increased incidence of mortality among patients taking other diuretics as concomitant treatment with risperidone. Irrespective of treatment, dehydration was an overall risk factor for mortality and should therefore be avoided in elderly patients with dementia (see section 4.3 Contraindications).

Photosensitivity: Cases of photosensitivity reactions have been reported. If photosensitivity reaction occurs during treatment, it is recommended to stop the treatment. If a re-administration is deemed necessary, it is recommended to protect exposed areas to the sun or to artificial UVA.

Furosemide 10 mg/ml Solution for Injection (2ml, 4ml and 5ml ampoule)

This medicinal product contains less than 1 mmol sodium (23 mg) per ampoule i.e. essentially "sodium free". Furosemide 10 mg/ml Solution for Injection (25 ml vial)

This medicinal product contains approximately 93 mg of sodium per vial. To be taken into consideration by patients on a controlled sodium diet.

4.5 Interaction with other Medicinal products and other forms of Interaction

Use during pregnancy

Furosemide should not be given during pregnancy unless there are compelling medical reasons. Furosemide crosses the placental barrier, and can therefore cause a diuresis of the fetus. Treatment during pregnancy requires monitoring of fetal growth.

Treatment of pregnancy hypertension and oedema is in general not recommended, as physiological hypovolemia can be induced which causes reduction of placental perfusion.

If use of furosemide is essential for the treatment of cardiac or renal insufficiency during pregnancy, careful monitoring of electrolytes, haematocrit and fetal growth is essential. Possible displacement of bilirubin from albumin binding and thus elevated risk of nuclear icterus in hyperbilirubinaemia is discussed for furosemide. Furosemide can predispose the fetus to hypercalciuria, nephrocalcinosis, and secondary hyperparathyroidism.

Furosemide reaches 100% of the maternal serum concentration in cord blood. No malformations in humans which might be associated with exposure to furosemide have been reported to date. However, there is limited experience to allow a conclusive evaluation of a potential damaging effect in the embryo/fetus.

Use during lactation

Furosemide passes into breast milk and may inhibit lactation. Women must not breast-feed if they are treated with furosemide (see section 4.3).

4.7 Effects on ability to drive and use machines

Furosemide has negligible influence on the ability to drive and use machines.

Patients respond individually to Furosemide.

The ability to drive or operate machines can incidentally be reduced because of treatment with furosemide, especially at the start of therapy, change of medication or in combination with alcohol.

4.6 Fertility, pregnancy and lactation

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4.8 Undesirable Effects

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The evaluation of adverse reactions is based on the following definition of frequency:

Very common (≥1/10)

Common (≥1/100 to <1/10)

Uncommon (≥1/1,000 to <1/100)

Rare (≥1/10,000 to <1/1,000)

Very rare (<1/10,000); not known (cannot be estimated from the available data).

Blood and lymphatic system disorders

Uncommon: thrombocytopenia; thrombocytopenia may become manifest, especially with an increase of haemorrhage tendency.

Rare: eosinophilia, leukopenia, bone marrow depression; occurrence of this symptom necessitates withdrawal of treatment.

Very rare: haemolytic anaemia, aplastic anaemia, agranulocytosis.

Severe fluid depletion may lead to haemoconcentration with a tendency for thromboses to develop especially in elder patients.

Immune system disorders

Rare: severe anaphylactic and anaphylactoid reactions such as anaphylactic shock (for treatment see section 4.9).

Endocrine disorders

Glucose tolerance may decrease with furosemide. In patients with diabetes mellitus this may lead to a deterioration of the metabolic control; latent diabetes mellitus may become manifest.

Metabolism and nutrition disorders

Hypokalaemia, hyponatraemia and metabolic alkalosismay occur, especially after prolonged therapy or when high doses are administered. Regular monitoring of serum electrolytes (especially potassium, sodium and calcium) is therefore indicated.

Potassium depletion may occur, especially due to poor potassium diet. Particulary when the supply of potassium is concomitantly reduced and/or extrarenal potassium losses are increased (e.g. in vomiting or chronic diarrhoea)

hypokalaemia may occur as a result of increased renal potassium losses.

Underlying disorders (e.g. cirrhotic disease or heart failure), concomitant medication (see section 4.5) and nutrition may cause predisposition to potassium deficiency. In such cases, adequate monitoring is necessary as well as therapy substitution.

As a result of increased renal sodium losses, hyponatraemia with corresponding symptoms may occur, particularly if the supply of sodium chloride is restricted.

Increased renal calcium losses can lead to hypocalcaemia, which may induce tetania in rare cases.

In patients with increased renal magnesium losses, tetania or cardiac arrhythmias were observed in rare cases as a consequence of hypomagnesaemia.

Uric acid levels may increase and gout attacks may occur.

Metabolic alkalosis may develop, or pre-existing metabolic alkalosis (for e.g. decompensated hepatic cirrhosis) may become more severe with furosemide.

Nervous system disorders

Rare: paraesthesia, vertigo, dizziness, sleepiness, confusion, sensations of pressure in the head.

Not known: Dizziness, fainting and loss of consciousness (caused by symptomatic hypotension)

Eye disorders

Rare: aggravation of myopia, blurred vision; disturbances of vision with hypovolaemia symptoms.

Ear and labyrinth disorders

Rare: dysacusis and/or syrigmus (tinnitus aurium) due to furosemide are rare and usually transitory; incidence is higher in rapid intravenous administration, particularly in patients with renal failure or hypoproteinaemia (e.g. in nephrotic syndrome).

Uncommon: deafness (sometimes irreversible)

Cardiac disorders

In particular, at the initial state of treatment and in elderly, a very intense diuresis may cause a reduction in blood pressure which, if pronounced may cause signs and symptoms such as orthostatic hypotension, acute hypotension, sensations of pressure in the head, dizziness, circulatory collapse, thrombophlebitis or sudden death (with i.m. or i.v. administration).

Gastrointestinal disorders

Rare: nausea, vomiting, diarrhoea, anorexia, gastric distress, constipation, dry mouth.

Hepato-biliary disorders

Very rare: acute pancreatitis, intrahepatic cholestasis, cholestasis jaundice, hepatic ischaemia, increases in hepatic transaminases.

Skin and subcutaneous tissue disorders

Uncommon: pruritus, dermal and mucosal reactions (e.g. bullous exanthema, rash, urticaria, purpura, erythema multiforme, exfoliative dermatitis, photosensitivity)

Rare: vasculitis, lupus erythematosus exacerbation or activation.

Not known: acute generalised exanthematous pustulosis (AGEP)

Musculoskeletal and connective tissue disorders

Rare: leg muscle cramps, asthenia. chronic arthritis.

Renal and urinary disorders

Diuretics may exacerbate or reveal acute retention of urine symptoms (bladder-emptying disorders, prostatic hyperplasia or narrowing of the urethra), vasculitis, glycosuria, transitorily increase of blood creatinine and urea levels.

Rare: interstitial nephritis.

Pregnancy, puerperium and perinatal conditions

Premature infants treated with furosemide may develop nephrocalcinosis and/or nephrolithiasis; due to calcium deposit in renal tissue.

In premature infants with respiratory distress syndrome, diuretic treatment in the first weeks of life with furosemide can increase the risk of persistent ductus arteriosus Botalli.

General disorders and administration site conditions

Rare: febrile conditions; following i.m. injection local reactions such as pain may appear.

Investigations

Rare: serum cholesterol and triglyceride levels may rise during furosemide treatment.

4.9 Overdose

The clinical picture in acute or chronic overdose depends primarily on the extent and consequences of electrolyte and fluid loss (e.g. hypovolaemia, dehydration, haemoconcentration, cardiac arrhythmias - including AV blockage and ventricular fibrillation) due to excessive diuresis.

Symptoms:

Symptoms of these disturbances include severe hypotension (progressing to shock), acute renal failure, thrombosis, delirious states, flaccid paralysis, apathy and confusion.

Treatment:

At the first signs of shock (hypotension, sudoresis, nausea, cyanosis) the injection should be immediately interrupted, place the patient head down and allow free breathing.

Fluid replacement and correction of the electrolyte imbalance; monitoring of metabolic functions, and maintenance of urinary flux.

Medicinal treatment in case of anaphylactic shock: dilute 1 ml of 1:1000 adrenaline solution in 10 ml and inject slowly 1 ml of the solution (corresponding to 0.1 mg of adrenaline), control pulse and tension and monitor eventual arrhythmias. Adrenaline administration may be repeated, if necessary. Subsequently, inject intravenously a glucocorticoid (for example 250 mg of methylprednisolone), repeating if necessary. Adapt the above-mentioned dosages for children, according body weight.

Correct hypovolaemia with available means and complement with artificial ventilation, oxygen and in case of anaphylactic shock with anti-histamines.

No specific antidote to furosemide is known. If overdose during parenteral treatment has taken place, in principle the treatment consists on follow up and supportive therapy. Haemodialysis does not accelerate furosemide elimination.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Diuretic, Sulfonamides, plain

ATC code: C03CA01

5.2 Pharmacokinetic Properties

Distribution

Furosemide distribution volume is 0.1 to 1.2 litres per kg of body weight. The distribution volume may be increased depending on the concomitant illness.

Protein binding (mostly to albumin) is higher than 98%.

Elimination

Furosemide is mostly eliminated as the non-conjugated form, mainly through secretion at the proximal tube. After intravenous administration, 60% to 70% of furosemide is eliminated by this manner. The glucuronic metabolite of furosemide represents 10% to 20% of the recovered substances in the urine. The remaining dose is eliminated in the faeces, probably after biliary secretion. After intravenous administration, the plasma half-life of furosemide ranges from 1 to 1.5 hours.

Furosemide is excreted in breast milk. It crosses the placental barrier transferring itself slowly to the foetus. Furosemide achieves similar concentrations in the mother, foetus and newborn.

Renal impairment

In case of renal impairment, furosemide´s elimination is slower and its half-life is increased. In patients with endstage renal disease the average half-life is 9.7 hours. In several multi-organ failure the half life may range from 20- 24 hours.

In case of nephrotic syndrome, the lower concentration of plasma proteins leads to higher concentrations of unbound furosemide . On the other hand, the efficiency of furosemide is reduced in these patients, due to intratubular albumin binding and to reduced tubular secretion.

Furosemide exhibits low dialysis in patients undergoing haemodialysis, peritoneal dialysis or CAPD (Chronic Ambulatory Peritoneal Dialysis).

Hepatic impairment

In case of hepatic impairment, furosemide´s half-life increases 30% to 90%, mainly due to the higher distribution volume. Biliary elimination might be reduced (up to 50%). In this group of patients, there is a wider variability of the pharmacokinetic parameters.

Congestive heart failure, severe hypertension, elderly

Furosemide elimination is slower due to reduced renal function in patients with congestive heart failure, severe hypertension or in elderly.

Premature infants and new-born

Depending on the maturity of the kidney, elimination of furosemide may be slow. In case of children with insufficient capacity of glucuronidation, the metabolism of the drug is also reduced. In term neonates the half-life is generally less than 12 hours.

5.3 Preclinical safety data

Chronic toxicity studies in the rat and dog led to renal alterations (among others fibrous degeneration and renal calcification). Furosemide did not show genotoxic or carcinogenic potential.

In reproductive toxicology studies, a reduced number of differentiated glomeruli, skeletal anomalies of the scapulae, humerus and ribs (induced by hypokalaemia) were seen in fetal rats, as well as hydronephrosis that occurred in fetal mice and rabbits after administration of high doses. The results of a mouse study and one of the three rabbit studies showed an increased incidence and severity of hydronephrosis (distention of the renal pelvis and, in some cases, of the ureters) in fetuses derived from the treated dams as compared with those from the control group. Preterm rabbits given furosemide had a higher incidence of intraventricular haemorrhage than saline-treated littermates, possibly due to furosemide-induced intracranial hypotension.

6. PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities:

Furosemide may precipitate out of solution in fluids of low pH.

6.3 Special Precautions for Storage

Do not store above 30°C.

Do not refrigerate.

Keep the ampoules in the outer carton in order to protect from light

6.4 Nature and Contents of Container

2ml Amber coloured round shaped semi-transparent glass ampoules having a constriction at neck region free from scratch. Free from glass particles.

6.5 Special Precautions for Disposal and Other Handling

For intravenous injection under medical direction.

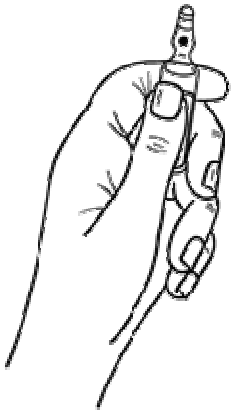
Instructions to open the ampoule:

Ampoules are equipped with the OPC (One Point Cut) opening system and must be opened using the following instructions:

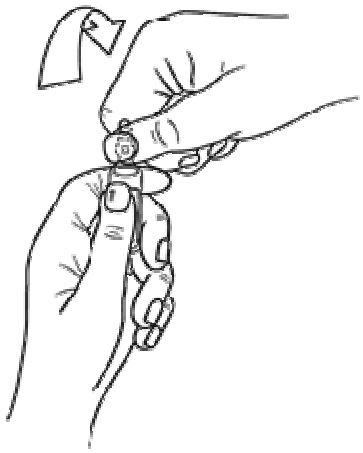
• hold with the hand the bottom part of the ampoule as indicated in picture 1

• put the other hand on the top of the ampoule positioning the thumb above the coloured point and press as indicated in picture 2

Picture 1



Picture 2



7. MARKETING AUTHORISATION HOLDER

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Fax: +91-22-26780784

E Mail: mail@cironpharma.com

Website : www.cironpharma.com

8. MARKETING AUTHORISATION NUMBER(S)

None

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Not applicable