AVENACY

Furosemide

Injection, USP

20 mg

NDC 83634-302-02
20 mg per 2 mL

DESCRIPTION	Single-Dose Vial
CONCENTRATION	10 mg per mL
CLOSURE	13 mm
UNIT OF SALE	25 Vials
BAR CODED	Yes
STORAGE	Room Temp.

40 mg

NDC 83634-302-04
40 mg per 4 mL

DESCRIPTION	Single-Dose Vial
CONCENTRATION	10 mg per mL
CLOSURE	13 mm
UNIT OF SALE	25 Vials
BAR CODED	Yes
STORAGE	Room Temp.

100 mg

NDC 83634-302-10
100 mg per 10 mL

DESCRIPTION	Single-Dose Vial
CONCENTRATION	10 mg per mL
CLOSURE	20 mm
UNIT OF SALE	25 Vials
BAR CODED	Yes
STORAGE	Room Temp.

• AP RATED • PRESERVATIVE-FREE •
• NOT MADE WITH NATURAL RUBBER LATEX •

PLEASE SEE IMPORTANT SAFETY INFORMATION ATTACHED, INCLUDING BOXED WARNING.
VISIT WWW.AVENACY.COM/PRODUCTS/FUROSEMIDE-INJECTION-USP FOR FULL PRESCRIBING INFORMATION.

ORDER THROUGH YOUR WHOLESALER:

STRENGTH	Cardinal	Cencora/ABC	McKesson	Morris & Dickson
20 mg per 2 mL	5942628	10292486	2982189	435313
40 mg per 4 mL	5942636	10292447	2982197	435339
100 mg per 10 mL	5908603	10287288	2920130	367011

ORDER DIRECT: info@avenacy.com

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FUROSEMIDE Injection, USP

INDICATION AND USAGE

Parenteral therapy should be reserved for patients unable to take oral medications or for patients in emergency clinical situations.

Furosemide is indicated in adults and pediatric patients for the treatment of edema associated with congestive heart failure, cirrhosis of the liver, and renal disease, including nephrotic syndrome. Furosemide is particularly useful when an agent with greater diuretic potential is desired. Furosemide is indicated as adjunctive therapy in acute pulmonary edema.

WARNING

FUROSEMIDE IS A POTENT DIURETIC WHICH, IF GIVEN IN EXCESSIVE AMOUNTS, CAN LEAD TO A PROFOUND DIURESIS WITH WATER AND ELECTROLYTE DEPLETION. THEREFORE, CAREFUL MEDICAL SUPERVISION IS REQUIRED AND DOSE AND DOSE SCHEDULE MUST BE ADJUSTED TO THE INDIVIDUAL PATIENT'S NEEDS.

CONTRAINDICATIONS

- Furosemide is contraindicated in patients with anuria and in patients with a history of hypersensitivity to furosemide.

WARNINGS

- Furosemide therapy should be initiated in the hospital for patients with cirrhosis or ascites.
- In patients with hepatic coma or electrolyte depletion, furosemide therapy should not be initiated until the patient is stabilized, and strict monitoring of fluid and electrolyte balance should occur during the period of diuresis.
- Hypokalemia and metabolic alkalosis can be prevented with supplemental potassium chloride or an aldosterone antagonist, if required.
- If increasing azotemia and oliguria occur during treatment of severe progressive renal disease, furosemide should be discontinued.
- Cases of tinnitus and reversible or irreversible hearing impairment and deafness have been reported. Furosemide ototoxicity is associated with rapid injection, severe renal impairment, the use of higher than recommended doses, hypoproteinemia, or concomitant therapy with ototoxic drugs. If the physician elects to use high dose parenteral therapy, controlled intravenous infusion is advisable (for adults, an infusion rate not exceeding 4 mg furosemide per minute has been used).
- In premature neonates with respiratory distress syndrome, diuretic treatment with furosemide in the first few weeks of life may increase the risk of persistent patent ductus arteriosus (PDA). Hearing loss in neonates has been associated with the use of furosemide injection.

PRECAUTIONS

- Excessive diuresis may cause dehydration and blood volume reduction with circulatory collapse and possibly vascular thrombosis and embolism, particularly in elderly patients. Because furosemide is excreted by the kidney and the risk of toxic reactions may be greater in patients with impaired renal function, care should be taken in dose selection and renal function should be monitored in elderly patients.
- Electrolyte depletion may occur during furosemide therapy, especially in patients receiving higher doses and a restricted salt intake. All patients receiving furosemide therapy should be observed for signs or symptoms of fluid or electrolyte imbalance.
- Furosemide can lead to a higher incidence of deterioration in renal function in patients at high risk for radiocontrast nephropathy, after receiving radiocontrast.
- The effect of furosemide may be weakened, and its ototoxicity can be potentiated in patients with hypoproteinemia.
- Asymptomatic hyperuricemia can occur, and gout may rarely be precipitated.
- Patients allergic to sulfonamides may also be allergic to furosemide. The possibility exists of exacerbation or activation of systemic lupus erythematosus.
- Patients should be observed regularly for the possible occurrence of blood dyscrasias, liver or kidney damage, or other idiosyncratic reactions.
- Patients should be informed that they may experience symptoms from excessive fluid and/or electrolyte losses. The postural hypotension that sometimes occurs can usually be managed by getting up slowly. Potassium supplements and/or dietary measures may be needed to control or avoid hypokalemia
- Furosemide may increase blood glucose levels in patients with diabetes mellitus.
- The skin of some patients may be more sensitive to the effects of sunlight while taking furosemide.
- Hypertensive patients should avoid medications that may increase blood pressure, including over-the-counter products for appetite suppression and cold symptoms.
- Laboratory tests such as serum electrolytes, CO2, creatinine, BUN, urine and blood glucose should be monitored frequently.
- In premature infants, furosemide may precipitate nephrocalcinosis/nephrolithiasis, therefore renal function must be monitored, and renal ultrasonography performed.
- Furosemide should not be used concomitantly with other ototoxic drugs like aminoglycosides or ethacrynic acid. Drugs that should be used with caution in patients receiving furosemide include salicylates/acetylsalicylic acid, cisplatin, tubocurarine, succinylcholine, lithium, angiotensin converting enzyme inhibitors/receptor blockers, antihypertensive agents, norepinephrine, chloral hydrate, phenytoin, methotrexate, cephalosporins, cyclosporine, and indomethacin.
- There are no adequate and well-controlled studies in pregnant women. Furosemide should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Treatment during pregnancy requires monitoring of fetal growth because of the potential for higher fetal birth weights.
- Because it appears in breast milk, caution should be exercised when furosemide is administered to a nursing mother. Furosemide may inhibit lactation.

ADVERSE REACTIONS

- Gastrointestinal reactions include hepatic encephalopathy, pancreatitis, jaundice, elevated liver enzymes, nausea, vomiting, diarrhea
- Dermatologic/hypersensitivity reactions include severe anaphylactic or anaphylactoid reactions, interstitial nephritis, Steven-Johnson Syndrome/toxic epidermal necrolysis, rash, pruritus, photosensitivity
- Central nervous system reactions include tinnitus/hearing loss, paresthesias, vertigo, headache, blurred vision

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- Hematologic reactions include thrombocytopenia, hemolytic anemia, leukopenia, eosinophilia, anemia, agranulocytosis
- Cardiovascular reactions include orthostatic hypotension
- Other reactions include electrolyte abnormalities, hyperglycemia, glycosuria, hyperuricemia, weakness, thrombophlebitis, fever

OVERDOSAGE

- The principal signs and symptoms of overdose with furosemide are dehydration, blood volume reduction, hypotension, electrolyte imbalance, hypokalemia and hypochloremic alkalosis, and are extensions of its diuretic action. Treatment of overdosage is supportive and consists of replacement of excessive fluid and electrolyte losses. Serum electrolytes, carbon dioxide level and blood pressure should be determined frequently. Adequate drainage must be assured in patients with urinary bladder outlet obstruction (such as prostatic hypertrophy). Hemodialysis does not accelerate furosemide elimination.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch. Or call 1-800-FDA-1088.

Please see full prescribing information for FUROSEMIDE Injection, USP.