HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Lasix® ONYU safely and effectively. See full prescribing information for Lasix® ONYU.

Lasix® ONYU (furosemide injection), for subcutaneous use
Initial U.S. Approval: 1968

INDICATIONS AND USAGE

Lasix ONYU is a loop diuretic indicated for the treatment of congestion due to fluid overload in adult patients with chronic heart failure. (1.1)

DOSAGE AND ADMINISTRATION

- The Infusor is pre-programmed to deliver 30 mg of Lasix ONYU over the first hour then 12.5 mg per hour for the subsequent 4 hours. (2.1)
- See Full Prescribing Information for important administration instructions. (2.2)

DOSAGE FORMS AND STRENGTHS

Injection: 80 mg per 2.67 mL in a single-dose prefilled cartridge co-packaged with a single-use Disposable Unit of the Infusor. (3)

CONTRAINDICATIONS

- Anuria. (4)
- Hypersensitivity to furosemide or medical adhesives. (4)
- Hepatic cirrhosis. (4)

WARNINGS AND PRECAUTIONS

- Fluid, Electrolyte, and Metabolic Abnormalities: Monitor serum electrolytes, CO_2, BUN, creatinine, glucose, and uric acid. (5.1)
- Worsening Renal Function: Monitor for dehydration and azotemia. (5.2)
- Ototoxicity: Avoid higher than recommended doses. (5.3, 7.1)
- Acute Urinary Retention: Monitor patients with symptoms of urinary retention. (5.4)

ADVERSE REACTIONS

The most common adverse reactions during treatment with the Lasix ONYU Infusor were administration site and skin reactions: erythema, bruising, edema, and infusion site pain. (6)

To report SUSPECTED ADVERSE REACTIONS, contact SQ Innovation, at 1-855-452-7496 or FDA at 1-800- FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Aminoglycoside antibiotics: Increased potential ototoxicity of the antibiotics. Avoid combination. (7.1)
- Ethacrynic acid: Risk of ototoxicity. Avoid combination. (7.1)
- Salicylates: Risk of salicylate toxicity. (7.1)
- Cisplatin and nephrotoxic drugs: Risk of ototoxicity and nephrotoxicity. (7.1)
- Lithium: Risk of lithium toxicity. (7.1)
- Renin-angiotensin inhibitors: Increased risk of hypotension and renal failure. (7.1)
- Adrenergic blocking drugs: Risk of potentiation. (7.1)
- Drugs undergoing renal tubular secretion: Risk of toxicity potentiation. (7.1)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: xx/2024

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION (FPI)

1 INDICATIONS AND USAGE

1.1 Congestion

Lasix ONYU is indicated for the treatment of congestion due to fluid overload in adult patients with chronic heart failure.

2 DOSAGE AND ADMINISTRATION

2.1 Dosage

The Infusor with single-dose prefilled cartridge delivers 30 mg of Lasix ONYU over the first hour followed by 12.5 mg per hour for the subsequent 4 hours *[see Clinical Pharmacology (12)]*. Administer Lasix ONYU once or twice daily as needed for fluid overload.

2.2 Important Administration Instructions

Lasix ONYU is intended for use in a setting where the patient can limit their activity for the duration of administration.

The Infusor for Lasix ONYU is not compatible with use in an MRI setting.

Inspect Lasix ONYU prefilled cartridge prior to administration. Lasix ONYU is a clear to slightly yellow solution. Do not use Lasix ONYU if solution is discolored or cloudy *[see Description (11)]*.

Refer to the Instructions for Use for additional information.

Push the Lasix ONYU prefilled cartridge into Disposable Unit. Slide the Reusable Unit and Disposable Unit together until the Status Light on the Reusable Unit turns on. The Infusor will remain ready to start infusion for 7 hours.

Peel away the paper liner on the Infusor and apply onto a clean, dry area of the abdomen between the top of the beltline and the bottom of the ribcage that is not tender, bruised, red, or indurated. Make sure the Status Lights and the Start/Stop Button are facing up in a horizontal position.
Start the injection by firmly pressing and holding the Start/Stop Button until you hear the motor and see the blue Status Light change to flashing slowly.

Do not remove until the injection is complete which is signaled by the solid blue Status Light and the OK tone (one long beep).

Rotate the site of each subcutaneous administration.

3 DOSAGE FORMS AND STRENGTHS

Injection: 80 mg per 2.67 mL as a clear to slightly yellow solution in a single-dose prefilled cartridge co-packaged with a single-use Disposable Unit of the Infusor.

4 CONTRAINDICATIONS

- Lasix ONYU is contraindicated in patients with anuria.
- Lasix ONYU is contraindicated in patients with a history of hypersensitivity to furosemide or medical adhesives.
- Lasix ONYU is contraindicated in patients with hepatic cirrhosis.

5 WARNINGS AND PRECAUTIONS

5.1 Fluid, Electrolyte, and Metabolic Abnormalities

Furosemide may cause fluid, electrolyte, and metabolic abnormalities such as hypovolemia, hypokalemia, azotemia, hyponatremia, hypochloremic alkalosis, hypomagnesemia, hypocalcemia, hyperglycemia, or hyperuricemia, particularly in patients receiving higher doses, patients with inadequate oral electrolyte intake, and in elderly patients. Excessive diuresis may cause dehydration and blood volume reduction with circulatory collapse and possible vascular thrombosis and embolism, particularly in elderly patients. Serum electrolytes, CO_2, BUN, creatinine, glucose, and uric acid should be monitored frequently during furosemide therapy.

5.2 Worsening Renal Function

Furosemide can cause dehydration and azotemia. If increasing azotemia and oliguria occur during treatment of severe progressive renal disease, furosemide should be discontinued *[see Clinical Pharmacology (12.3)]*.

5.3 Ototoxicity

Cases of tinnitus and reversible or irreversible hearing impairment and deafness have been reported with furosemide. Reports usually indicate that furosemide ototoxicity is associated with rapid injection, severe renal impairment, the use of higher than recommended doses, hypoproteinemia or concomitant therapy with aminoglycoside antibiotics, ethacrynic acid, or other 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) *[see Drug Interactions (7)]*.

5.4 Acute Urinary Retention

In patients with severe symptoms of urinary retention (because of bladder emptying disorders, prostatic hyperplasia, urethral narrowing), the administration of furosemide can cause acute urinary retention related to increased production and retention of urine. These patients require careful monitoring, especially during the initial stages of treatment.

6 ADVERSE REACTIONS

The following important adverse reactions are discussed elsewhere in the labeling:

- Fluid, Electrolyte, and Metabolic Abnormalities *[see Warnings and Precautions (5.1)]*.
- Ototoxicity *[see Warnings and Precautions (5.3)]*

The following adverse reactions associated with the use of furosemide were identified in clinical trials or post-marketing reports. Because these reactions were reported voluntarily from a population of uncertain size, it is not always possible to estimate their frequency reliably, or to establish a causal relationship to drug exposure.

Adverse reactions are categorized below by organ system and listed by decreasing severity.

Gastrointestinal System Reactions: pancreatitis, jaundice (intrahepatic cholestatic jaundice), increased liver enzymes, anorexia, oral and gastric irritation, cramping, diarrhea, constipation, nausea, vomiting.

Systemic Hypersensitivity Reactions: severe anaphylactic or anaphylactoid reactions (e.g., with shock), systemic vasculitis, interstitial nephritis, necrotizing angiitis.

Central Nervous System Reactions: tinnitus and hearing loss, paresthesias, vertigo, dizziness, headache, blurred vision, xanthopsia.

Hematologic Reactions: aplastic anemia, thrombocytopenia, agranulocytosis, hemolytic anemia, leukopenia, anemia, eosinophilia.

Dermatologic Hypersensitivity Reactions: toxic epidermal necrolysis, Stevens-Johnson Syndrome, erythema multiforme, drug rash with eosinophilia and systemic symptoms, acute generalized exanthematous pustulosis, exfoliative dermatitis, bullous pemphigoid, purpura, photosensitivity, rash.

Cardiovascular Reactions: orthostatic hypotension, increase in cholesterol and triglyceride serum levels.

Administration Site and Skin Reactions: erythema, bruising, edema, infusion site pain.
Other Reactions: glycosuria, muscle spasm, weakness, restlessness, urinary bladder spasm, thrombophlebitis, transient injection site pain following intramuscular injection, fever.

7 DRUG INTERACTIONS

7.1 Effects of Furosemide on Other Drugs

Table 1: Effects of Furosemide on Other Drugs

Drug/Substance Class or Name	Drug Interaction Effect	Recommendations
Aminoglycoside antibiotics	Furosemide may increase the ototoxic potential of aminoglycoside antibiotics, especially in the presence of impaired renal function *[see Warnings and Precautions (5.3)]*.	Avoid combination except in life-threatening situations.
Ethacrynic acid	Possibility of ototoxicity *[see Warnings and Precautions (5.3)]*.	Avoid concomitant use with ethacrynic acid.
Salicylates	May experience salicylate toxicity at lower doses because of competitive renal excretory sites.	Monitor for symptoms of salicylate toxicity.
Cisplatin	There is a risk of ototoxic effects if cisplatin and furosemide are given	

Drug/Substance Class or Name	Drug Interaction Effect	Recommendations
Cisplatin and nephrotoxic drugs	concomitantly *[see Warnings and Precautions (5.3)]*. Nephrotoxicity	Administer furosemide at lower doses and with positive fluid balance when used to achieve forced diuresis during cisplatin treatment. Monitor renal function.
Paralytic agents	Furosemide has a tendency to antagonize the skeletal muscle relaxing effect of tubocurarine and may potentiate the action of succinylcholine.	Monitor for skeletal muscle effect.
Lithium	Furosemide reduces lithium's renal clearance and adds a high-risk of lithium toxicity.	Avoid concomitant use with lithium.
Angiotensin converting enzyme inhibitors or angiotensin II receptor blockers	May lead to severe hypotension and deterioration in renal function, including renal failure.	Monitor for changes in blood pressure and renal function and interrupt or reduce the dosage of furosemide, angiotensin converting enzyme inhibitors, or angiotensin receptor blockers if needed.
Antihypertensive drugs	Furosemide may add to or potentiate the therapeutic effect of other antihypertensive drugs.	Monitor for changes in blood pressure and adjust the dose of other antihypertensive drugs if needed.
Adrenergic blocking drugs or peripheral adrenergic blocking drugs	Potentiation occurs.	Monitor for changes in blood pressure and adjust the dose of adrenergic blocking drugs if needed.
Norepinephrine	Furosemide may decrease arterial responsiveness (vasoconstricting effect) to norepinephrine.	Monitor blood pressure (or mean arterial pressure).
Chloral hydrate	In isolated cases, intravenous administration of furosemide within 24 hours of taking chloral hydrate may lead to flushing, sweating attacks, restlessness, nausea, increase in blood pressure, and tachycardia.	Concomitant use with chloral hydrate is not recommended.
Methotrexate and other drugs undergoing renal tubular secretion	Furosemide may decrease renal elimination of other drugs that undergo tubular secretion. High-dose treatment of furosemide may result in elevated serum levels of these drugs and may potentiate their toxicity.	Monitor serum levels of drugs undergoing renal tubular secretion and adjust the dose if needed.

Drug/Substance Class or Name	Drug Interaction Effect	Recommendations
Cephalosporin	Furosemide can increase the risk of cephalosporin-induced nephrotoxicity even in the setting of minor or transient renal impairment.	Monitor for changes in renal function.
Cyclosporine	Increased risk of gouty arthritis secondary to furosemide-induced hyperuricemia and cyclosporine impairment of renal urate excretion.	Monitor serum urate levels.
Thyroid hormones	High doses (> 80 mg) of furosemide may inhibit the binding of thyroid hormones to carrier proteins and result in transient increase in free thyroid hormones, followed by an overall decrease in total thyroid hormone levels.	Monitor the total thyroid hormone levels.

7.2 Effect of Other Drugs on Furosemide

Table 2: Effect of Other Drugs on Furosemide

Drug/Substance Class or Name	Drug Interaction Effect	Recommendations
Phenytoin	Phenytoin interferes directly with renal action of furosemide.	Monitor diuretic effects of furosemide and adjust the dose of furosemide if needed.
Methotrexate and other drugs undergoing renal tubular secretion	May reduce the effect of furosemide. High-dose treatment of methotrexate and these other drugs may result in elevated serum levels of furosemide and may potentiate the toxicity of furosemide.	Monitor for enhanced toxicity of furosemide.
Indomethacin	Coadministration of indomethacin may reduce the natriuretic and antihypertensive effects of furosemide in some patients by inhibiting prostaglandin synthesis. Indomethacin may also affect plasma renin levels, aldosterone excretion, and renin profile evaluation.	Patients receiving both indomethacin and furosemide should be observed closely to determine if the desired diuretic and/or antihypertensive effect of furosemide is achieved.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Available data from published observational studies, case reports, and post marketing reports, from decades of use, have not demonstrated a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes with furosemide use during pregnancy. Untreated congestive heart failure can lead to adverse outcomes for the mother and the fetus (*see Clinical Considerations)*.

In animal reproduction studies, furosemide has been shown to cause unexplained maternal deaths and abortions in rabbits when administered orally during organogenesis at 4 times a human i.v. dose of 80 mg based on body surface area (BSA) and oral bioavailability corrections, presumably secondary to volume depletion (*see Data)*.

The background risk for major birth defects and miscarriage for the indicated populations is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in the clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Clinical Considerations

Disease-associated Maternal and/or Embryo/fetal Risk

Pregnant women with congestive heart failure are at increased risk for pre-term birth. Stroke volume and heart rate increase during pregnancy, increasing cardiac output, especially during the first trimester.
Clinical classification of heart disease may worsen with pregnancy and lead to maternal death and/or stillbirth. Closely monitor pregnant patients for destabilization of their heart failure.

Data

Animal Data

The effects of furosemide on embryonic and fetal development and on pregnant dams were studied in mice, rats, and rabbits.

Furosemide caused unexplained maternal deaths and abortions in rabbits at the lowest dose of 25 mg/kg (approximately 4 times the human i.v. dose of 80 mg based on BSA and oral bioavailability corrections). In another study, a dose of 50 mg/kg (approximately 7 times a human i.v. dose of 80 mg based on BSA and oral bioavailability corrections) also caused maternal deaths and abortions when administered to rabbits between Days 12 and 17 of gestation. In a third study, none of the pregnant rabbits survived an oral dose of 100 mg/kg. Data from the above studies indicate fetal lethality that can precede maternal deaths.

The results of the mouse study and one of the three rabbit studies also showed an increased incidence and severity of hydronephrosis (distention of the renal pelvis and, in some cases, of the ureters) in fetuses of treated dams as compared with the incidence of fetuses from the control group.

8.2 Lactation

Risk Summary

The presence of furosemide has been reported in human breast milk. There are no data on the effects on the breastfed infant or the effects on milk production. Doses of furosemide associated with clinically significant diuresis may impair milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for furosemide and any potential adverse effects on the breastfed infant from furosemide or from the underlying maternal condition.

8.4 Pediatric Use

Safety and efficacy for pediatric use have not been established *[see Indications and Usage (1)]*.

8.5 Geriatric Use

Controlled clinical studies did not include sufficient numbers of subjects to determine whether subjects aged 65 and over respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for the elderly patients should be cautious, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

Lasix ONYU is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function *[see Clinical Pharmacology (12.3)]*.

10 OVERDOSAGE

The principal signs and symptoms of overdose with Lasix ONYU are dehydration, blood volume reduction, hypotension, electrolyte imbalance, hypokalemia, and hypochloremic alkalosis, and are extensions of its diuretic action.

The concentration of furosemide in biological fluids associated with toxicity or death is not known.

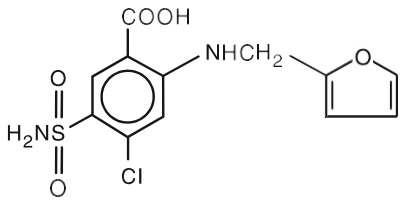
Treatment of overdosage is supportive and consists of replacement of excessive fluid and electrolyte losses. Serum electrolytes, carbon dioxide level, and blood pressure should be determined frequently. Adequate drainage must be assured in patients with urinary bladder outlet obstruction (such as prostatic hypertrophy).

Hemodialysis does not accelerate furosemide elimination.

11 DESCRIPTION

Lasix ONYU (furosemide injection) for subcutaneous use is a loop diuretic. Chemically, it is 4-chloro-N-furfuryl-5-sulfamoylanthranilic acid.

Furosemide is a white to slightly yellow crystalline powder. It is sparingly soluble in alcohol, freely soluble in dilute alkali solutions, and insoluble in dilute acids. The structural formula is as follows:



Molecular Formula:	Molecular Weight:
$C_{12}H_{11}ClN_2O_5S$	330.74 g/mol

Lasix ONYU is a single-dose prefilled cartridge co-packaged with a single-use Disposable Unit of the Infusor.

The single-dose prefilled cartridge contains 80 mg furosemide in a 2.67 mL sterile, clear to slightly yellow, and nonpyrogenic aqueous solution. The pH of Lasix ONYU, 7.5, differs from that of Furosemide Injection, USP. Each 1 mL dose of Lasix ONYU contains 30 mg of furosemide and the following inactive ingredients: betadex sulfobutyl ether sodium (300 mg), hydrochloric acid for pH adjustment if needed, sodium hydroxide for pH adjustment if needed, tromethamine (3.0 mg), and water for injection (q.s.).

Each single-dose of Lasix ONYU is administered via an electromechanical (battery powered, microprocessor controlled) Infusor, pre-programmed to deliver 80 mg of Lasix ONYU over 5-hours using a bi-phasic delivery profile. The Infusor consists of a custom Reusable Unit which can be used for close to 50 treatments. The Reusable Unit is used with a Disposable Unit and single-dose prefilled cartridge which are provided together for the user as a Lasix ONYU Kit. The Disposable Unit must be discarded after use.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Furosemide primarily inhibits the reabsorption of sodium and chloride in the proximal and distal tubules and in the loop of Henle. The high degree of diuresis is largely due to the unique site of action. The action on the distal tubule is independent of any inhibitory effect on carbonic anhydrase and aldosterone.

12.2 Pharmacodynamics

In patients with congestive heart failure, subcutaneous administration of Lasix ONYU (30 mg furosemide over the first hour followed by 12.5 mg per hour for the subsequent 4 hours, total 80 mg furosemide within 5 hours) produced similar diuresis and natriuresis to intravenous administration (single 80 mg bolus) at 8- and 24-hour post-dose. The duration of diuretic effect with Lasix ONYU is up to 8 hours or more after initiation of dosing.

12.3 Pharmacokinetics

Absorption

In patients with congestive heart failure, subcutaneous infusion of Lasix ONYU (30 mg furosemide over the first hour followed by 12.5 mg per hour for the subsequent 4 hours, 80 mg furosemide total), the bioavailability was 112% (90% CI: 104, 120%), with a median Tmax of 5 hours relative to 80 mg intravenous furosemide (single 80 mg bolus). The pharmacokinetic parameters of Lasix ONYU are presented in Table 3 below:

Table 3: Pharmacokinetic Data of Lasix ONYU Following Subcutaneous Infusion (n = 18)

Dose	Cmax (ng/mL)*	AUCt (ng×hr/mL)*	T1/2 (hr)*	AUC∞ (ng×hr/mL)*
Lasix ONYU: 30 mg subcutaneously infused over the first hour followed by 12.5 mg per hour for the subsequent 4 hours (total dose: 80 mg furosemide)	2010 ± 391	13000 ± 2510	3.7 ± 0.7	13100 ± 2550
Furosemide administered as single 80 mg bolus dose intravenously	13800 ± 4100	11900 ± 3380	3.7 ± 1.3	12000 ± 3400

*Mean ± SD.

The terminal half-life of furosemide is approximately 2 hours.

Distribution

Furosemide is extensively bound to plasma proteins, mainly to albumin. Plasma concentrations ranging from 1 mcg per mL to 400 mcg per mL are 91% to 99% bound in healthy individuals. The unbound fraction averages 2.3% to 4.1% at therapeutic concentrations.
Furosemide binding to albumin may be reduced in elderly patients.

Elimination

Significantly more furosemide is excreted in urine following the intravenous injection than after the tablet or oral solution.

Furosemide is predominantly excreted unchanged in the urine.

The renal clearance of furosemide after intravenous administration in older healthy male subjects (60 to 70 years of age) is significantly less than in younger healthy male subjects (20 to 35 years of age).

Metabolism

Furosemide glucuronide is the only or at least the major biotransformation product of furosemide in man.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Furosemide was tested for carcinogenicity by oral administration in one strain of mice and one strain of rats. A small but significantly increased incidence of mammary gland carcinomas occurred in female mice at a dose approximately 8 times a human i.v. dose of 80 mg based on BSA and oral bioavailability corrections. There were marginal increases in uncommon tumors in male rats at a dose of 15 mg per kg (slightly greater than the maximum human dose) but not at 30 mg per kg.

Mutagenesis

Furosemide was devoid of mutagenic activity in various strains of Salmonella typhimurium when tested in the presence or absence of an in vitro metabolic activation system, and questionably positive for gene mutation in mouse lymphoma cells in the presence of rat liver S9 at the highest dose tested. Furosemide did not induce sister chromatid exchange in human cells in vitro, but other studies on chromosomal aberrations in human cells in vitro gave conflicting results. In Chinese hamster cells it induced chromosomal damage but was questionably positive for sister chromatid exchange. Studies on the induction by furosemide of chromosomal aberrations in mice were inconclusive. The urine of rats treated with this drug did not induce gene conversion in Saccharomyces cerevisiae.

Impairment of Fertility

Furosemide produced no impairment of fertility in male or female rats, at 100 mg per kg per day (the maximum effective diuretic dose in the rat), approximately 7 times a human i.v. dose of 80 mg based on BSA and oral bioavailability corrections.

16 HOW SUPPLIED/STORAGE AND HANDLING

Lasix ONYU injection is a sterile, clear to slightly yellow, non-pyrogenic liquid supplied in a single-dose prefilled cartridge for subcutaneous infusion co-packaged with a Disposable Unit. The Infusor with single-dose prefilled cartridge is designed to deliver 80 mg of Lasix ONYU in 2.67 mL solution over 5 hours.

Lasix ONYU Kit: Carton containing one 80 mg/2.67 mL single-dose prefilled cartridge co-packaged with a Disposable Unit and two alcohol pads.	NDC 81137-001-15
Starter Kit: Carton containing three Lasix ONYU Kits co-packaged with one Reusable Unit and one wall charger.	NDC 81137-001-35

Store between 20°C and 25°C (68°F and 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [See USP Controlled Room Temperature]. Do not refrigerate or freeze.

Protect Lasix ONYU from light. Do not remove the prefilled cartridge from carton until it is ready for use. Do not use if the solution is discolored or cloudy. Protect the Infusor from water.

17 PATIENT COUNSELING INFORMATION

Advise the patient and/or caregiver to read the FDA-approved patient labeling [*Instructions for Use*].

Fluid, Electrolyte, and Metabolic Abnormalities

Advise patients 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 *[see Warnings and Precautions (5.1)]*.
Advise patients that furosemide may increase blood glucose levels and thereby affect urine glucose tests *[see Warnings and Precautions (5.1)]*.

Photosensitivity

The skin of some patients may be more sensitive to the effects of sunlight while taking furosemide *[see Adverse Reactions (6)]*.

Advise hypertensive patients to avoid medications that may increase blood pressure, including over-the-counter products for appetite suppression and cold symptoms *[see Drug Interactions (7)]*.

For more information about Lasix® ONYU, go to www.Lasix-ONYU.com or call 1-855-452-7496 (1-855-4LA-SIX6).

Lasix® ONYU (furosemide injection 80 mg/2.67 mL) for subcutaneous use

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