

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 edema 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)
- Lasix ONYU is not for chronic use and should be replaced with oral diuretics as soon as practical. (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, CO₂, 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)
- **Incomplete Dosing:** Fluid contact and certain patient movements during treatment may cause the On-body Infusor to prematurely terminate infusion. Ensure patients can detect and respond to alarms. (5.5)

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.

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FULL PRESCRIBING INFORMATION: CONTENTS*

1 INDICATIONS AND USAGE

1.1 Congestion

2 DOSAGE AND ADMINISTRATION

2.1 Dosage

2.2 Important Administration Instructions

3 DOSAGE FORMS AND STRENGTHS

4 CONTRAINDICATIONS

5 WARNINGS AND PRECAUTIONS

5.1 Fluid, Electrolyte, and Metabolic Abnormalities

5.2 Worsening Renal Function

5.3 Ototoxicity

5.4 Acute Urinary Retention

5.5 Incomplete Dosing

6 ADVERSE REACTIONS

7 DRUG INTERACTIONS

7.1 Effects of Furosemide on Other Drugs

7.2 Effect of Other Drugs on Furosemide

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

8.2 Lactation

8.4 Pediatric Use

8.5 Geriatric Use

8.6 Renal Impairment

8.7 Hepatic Impairment

10 OVERDOSAGE

11 DESCRIPTION

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

12.2 Pharmacodynamics

12.3 Pharmacokinetics

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

16 HOW SUPPLIED/STORAGE AND HANDLING

17 PATIENT COUNSELING INFORMATION

*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 edema 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 edema. Lasix ONYU is not for chronic use and should be replaced with oral diuretics as soon as practical.

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 [see *Warnings and Precautions (5.5)*].

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, any component of the Lasix ONYU formulation, or medical adhesives.

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, CO₂, 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, discontinue furosemide [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.

5.5 Incomplete Dosing

The Lasix ONYU Infusor should not come in contact with water or any other fluids (blood or drug product). Fluid contact with the Infusor circuit board can lead to device errors and premature termination of infusion.

The Lasix ONYU is intended for use in a setting where the patient can limit their activity for the duration of administration. Certain patient movements may cause interruption of device adherence to skin and premature termination of infusion.

Lasix ONYU should only be used in patients who can detect and respond to alarms to ensure a complete dose is administered.

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 angitis.

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 [<i>see Warnings and Precautions (5.3)</i>].	Avoid combination except in life-threatening situations.
Ethacrynic acid	Possibility of ototoxicity [<i>see Warnings and Precautions (5.3)</i>].	Avoid concomitant use with ethacrynic acid.

Drug/Substance Class or Name	Drug Interaction Effect	Recommendations
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 concomitantly [see <i>Warnings and Precautions</i> (5.3)].	
Cisplatin and nephrotoxic drugs	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	Potential 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	Monitor serum levels of drugs undergoing renal tubular secretion and adjust the dose if needed.

Drug/Substance Class or Name	Drug Interaction Effect	Recommendations
	treatment of furosemide may result in elevated serum levels of these drugs and may potentiate their toxicity.	
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)*].

8.6 Renal Impairment

Significantly reduced renal function can affect the response to furosemide. Lasix ONYU will deliver only an 80 mg dose of furosemide, and patients with significantly reduced renal function may require additional diuretic therapy.

8.7 Hepatic Impairment

In patients with hepatic cirrhosis and ascites, sudden alterations of fluid and electrolyte balance may precipitate hepatic encephalopathy and coma. Treat such patients in a setting where clinical status and electrolyte balance can be carefully monitored.

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.

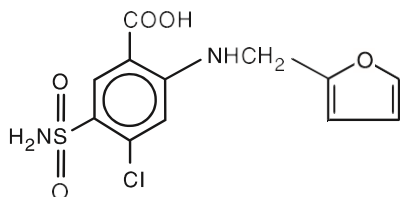
Treatment of overdosage is supportive and consists of replacement of excessive fluid and electrolyte losses. Serum electrolytes, carbon dioxide level, and blood pressure should be determined frequently. Adequate drainage must be assured in patients with urinary bladder outlet obstruction (such as prostatic 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:
 $C_{12}H_{11}ClN_2O_5S$

Molecular Weight:
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 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 NYHA Class II and Class III 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 at least 8 hours after initiation of dosing.

12.3 Pharmacokinetics

Absorption

In patients with NYHA Class II and Class III 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 T_{max} 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	C_{max} (ng/mL)*	AUC_t (ng×hr/mL)*	T_{1/2} (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.

The impact of subcutaneous edema at the administration site of Lasix ONYU on drug absorption is unknown.

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 humans.

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*].

Advise the patient that Lasix ONYU should not come into contact with water or other fluids. Patients should check the device for alarms to ensure a complete dose is administered [*see Warnings and Precautions (5.5)*].

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)*].

For more information about Lasix[®] ONYU, go to www.Lasix-ONYU.com or call 1-855-452-7496 (1-855-4LASIX6).



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

Manufactured for:
SQ Innovation, Inc.
20 Burlington Mall Road, Suite 220
Burlington, MA 01803
USA

Patent Protected
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Instructions for Use

Lasix[®] ONYU (lay-six on-yoo)

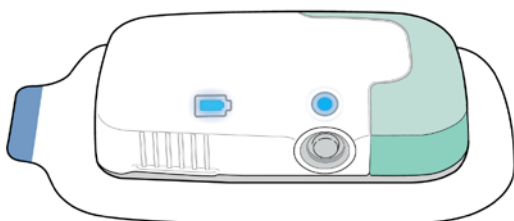
(furosemide injection)

80 mg/2.67 mL

(30 mg/mL)

**for subcutaneous use
with Infusor**

These Instructions for Use contains information
on how to use Lasix ONYU with the Infusor.



Contact Information:

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Phone: 1-855-452-7496 (1-855-4LASIX6)

www.Lasix-ONYU.com

Table of Contents

- 1. Important Information You Need to Know 3**
 - Before Using the Lasix ONYU Infusor 4
 - Before Starting a Treatment 5
 - During a Treatment..... 5
- 2. How to Use the Lasix ONYU Infusor 7**
 - Inside the Box 8
 - Get to Know the Lasix ONYU Infusor Parts 10
 - Get Ready for the Infusion..... 11
 - Prepare the Medicine 12
 - Prepare the Lasix ONYU Infusor..... 15
 - Prepare the Application Site 16
 - Attach the Lasix ONYU Infusor 17
 - Start the Infusion 18
 - During the Infusion 20
 - End the Infusion 21
 - Confirm the Infusion Worked 22
 - Throw Away (Disposal), Cleaning, and Storage..... 23
- 3. Troubleshooting 26**
 - Customer Service Contact Information..... 27
 - Lights and Tones Table..... 28
 - Checking the Reusable Unit Battery 29
 - The Reusable Unit Has Expired 31
 - The Status Light is Flashing Red 32
 - You Can See the Needle..... 34
 - How to Stop the Lasix ONYU Infusor Early..... 36
 - You Did not Urinate (Pee) Much During Infusion 37
 - The Reusable Unit Does Not Light Up..... 38
 - The Lasix ONYU Infusor Will Not Start Infusion 40

Table of Contents (continued)

4. **Technical Information** 41

 Part Numbers..... 42

 Specifications 43

 California Proposition 65 44

 Symbols..... 45

 EMC Safety..... 47

5. **Additional Information** 54

 Watch Training Video 55

 Warranty Information..... 56

Chapter 1

Important Information You Need to Know

1 Important Information You Need to Know

Before Using the Lasix ONYU Infusor

- Keep the Lasix ONYU Infusor out of sight and reach of children.
- The Lasix ONYU treatment is for adult patients only as prescribed by a healthcare provider.
- **For subcutaneous (under the skin) use only.** The Lasix ONYU Infusor delivers the medicine just under the skin.
- **Use on the stomach only.** Do not use on any other area of the body.
- The Lasix ONYU Infusor is intended to be used by a single person and **should not be shared.**
- **Do not use** the Prefilled Cartridge **if the solution is cloudy, yellow-brown or contains floating particles.** It should be clear or light yellow. If it is not clear or light yellow, contact your healthcare provider to get a new one.
- **Do not use** any part of the Lasix ONYU Infusor **if it has expired.** If it is expired, contact your healthcare provider to get a new one.
- **Do not use** any part of the Lasix ONYU Infusor (Prefilled Cartridge, Disposable Unit, Reusable Unit or Charger) **if it appears to be broken or damaged** or does not work right. Use a new one or call SQ Innovation at 1-855-452-7496.
- **Do not use** a Disposable Unit if it was dropped as it may be damaged or contaminated. Use a new one.
- **Do not use** the Lasix ONYU Infusor **if you can see the needle.** Do not touch the needle or put the Lasix ONYU Infusor on your stomach, as you may get an injury. Go to **Troubleshooting: You Can See the Needle** for instructions on what to do.
- **Do not use more than 1 Lasix ONYU Infusor at a time.**
- **Do not do** more than 2 infusions in a 24-hour period.
- **Do not use a Disposable Unit or Prefilled Cartridge more than 1 time.**

1 Important Information You Need to Know (continued)

Warning: Do not use insulin cartridges or other medicine cartridges **in the Lasix ONYU Infusor**. Doing so could cause severe injury. Only use the Lasix ONYU Prefilled Cartridge with the Lasix ONYU Infusor.

Before Starting a Treatment

- **Talk with your healthcare provider before using** the Lasix ONYU Infusor.
Do not start an infusion unless directed to do so by your healthcare provider.
- **A healthcare provider should train you** before using the Lasix ONYU Infusor by yourself.
- **Read the step-by-step instructions** (go to **Chapter 2: How to Use the Lasix ONYU Infusor**) **before using** the Lasix ONYU Infusor by yourself.
- You may watch the optional training video.



Training Video

Scan the code with your phone or visit the website:
www.Lasix-ONYU.com/infusor-training

During a Treatment

- **Start the infusion within 7 hours** of preparing the Lasix ONYU Infusor.
- The infusion will last about 5 hours. During this time, you should limit your activities so that your bending movements are limited. Wearing the Lasix ONYU Infusor while riding in a car or airplane is not recommended. Be sure you have access to a bathroom after starting the infusion. You should urinate (pee) a lot and will need to make frequent bathroom visits.
- Frequent urination is to be expected during use of the Lasix ONYU Infusor. **Be sure you have access to a bathroom for up to 8 hours** after starting the infusion.
- **Call your healthcare provider if you did not urinate a lot** (at least 2 times during the 5-hour infusion).

1 Important Information You Need to Know (continued)

- **Do not** apply lotions, oils, or ointments to the stomach area where you will apply the Lasix ONYU Infusor.
- **Do not get the Lasix ONYU Infusor wet.** Doing so may damage the Lasix ONYU Infusor. Do not shower, bathe, or swim while wearing the Lasix ONYU Infusor.
- **Do not remove the Lasix ONYU Infusor** from the stomach until the infusion is done. Removing the Lasix ONYU Infusor before stopping it will expose the needle, and may injure you or others. Go to **How to Stop the Lasix ONYU Infusor Early** if you need to stop the infusion early.
- **Do not** use the Lasix ONYU Infusor in or around a Magnetic Resonance Imaging (MRI) machine.
- **Do not** use the Lasix ONYU Infusor within 12 inches of mobile phones, tablets, computers, or wireless accessories (for example: TV remote control, Bluetooth computer keyboard or mouse) during the 5-hour infusion. It may cause the Lasix ONYU Infusor to break.

Chapter 2

How to Use the Lasix ONYU Infusor

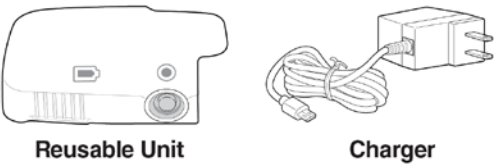
2 Inside the Box

Contents of the Lasix ONYU Kit



Note: The Single-Dose Prefilled Cartridge is referred to as Prefilled Cartridge throughout this Instructions for Use.

Contents of the Reusable Unit and Charger Box



2 Inside the Box (continued)

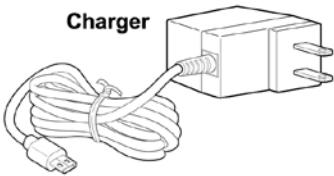
Contents of the Lasix ONYU Starter Kit



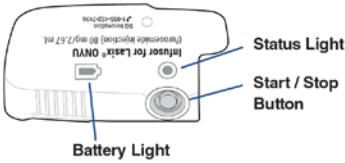
Supplies not included:

- Cotton ball and small adhesive bandage (if needed) for **Step 21 in End the Infusion.**
- You will also need a sharps disposal container for **Step 25 in Throw Away (Disposal), Cleaning, and Storage.** You may obtain a free sharps disposal container from SQ Innovation. Visit www.sqinnovation.com/sharps/ or call 1-855-452-7496 to have a container mailed to you at no charge.

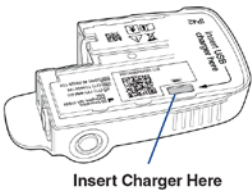
2 Get to Know the Lasix ONYU Infusor Parts



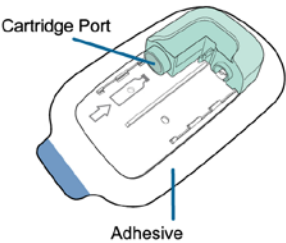
Reusable Unit (Front)



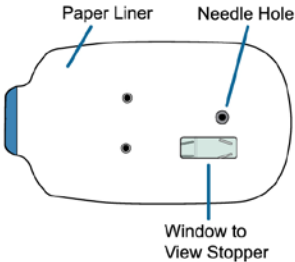
Reusable Unit (Back)



Disposable Unit (Front)



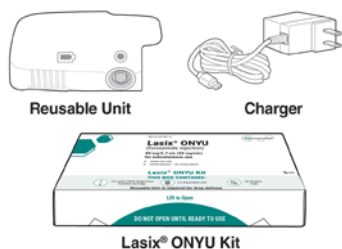
Disposable Unit (Back)



Follow the step-by-step instructions starting on the next page >>

2 Get Ready for the Infusion

Do not start an infusion unless directed to do so by your healthcare provider.

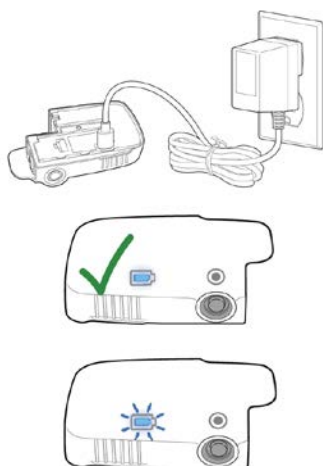


Step 1

Gather the white Reusable Unit, Charger, and 1 Lasix ONYU Kit.

Only use the Charger that has been provided.

Do not use if the Disposable Unit was dropped or if any parts appear to be broken or **damaged**. Use a new one.



Step 2

Charge the Reusable Unit.

Plug the Charger into the back of the white Reusable Unit and a power outlet. Check the Battery Light:

- When the **Battery Light turns solid blue**, **unplug the charger** from the Reusable Unit. The Reusable Unit is ready to use.
- If the **Battery Light is flashing blue**, **wait** for charging to finish.
- If any lights are **red**, **unplug the Charger** and plug it back in. If the lights are still red, go to **Troubleshooting: Lights and Tones Table** for instructions.

Always charge the Reusable Unit before each infusion.

2 Prepare the Medicine



Step 3

Wash your hands with soap and water.



Step 4

Check the expiration date on the Lasix ONYU Kit.

Do not use if the expiration date has passed.



Alcohol Pads



Single-Dose Prefilled Cartridge



Disposable Unit

Step 5

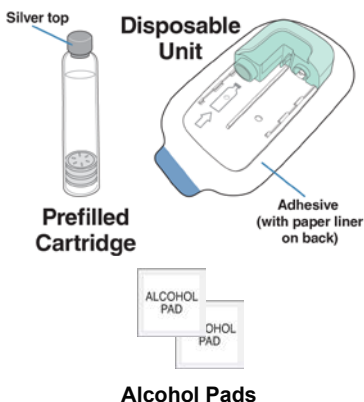
Gather all supplies needed. On a clean, flat, well-lit work surface, **open 1 Lasix ONYU Kit** and remove the contents.

Do not open the contents until you are ready to start the infusion.

Do not use the Disposable Unit if the sealed packaging appears to be damaged. Use a new one.

Do not use the Disposable Unit if it was dropped or if any parts appear to be broken. Use a new one.

2 Prepare the Medicine (continued)



Step 6

Remove the Prefilled Cartridge, Disposable Unit, and 2 alcohol pads from packaging:

- Remove the Prefilled Cartridge from its box and sealed tray.
- Remove the Disposable Unit from its sealed package.

Do not remove the paper liner from the back of the Disposable Unit.



Step 7

Check the Prefilled Cartridge appearance.

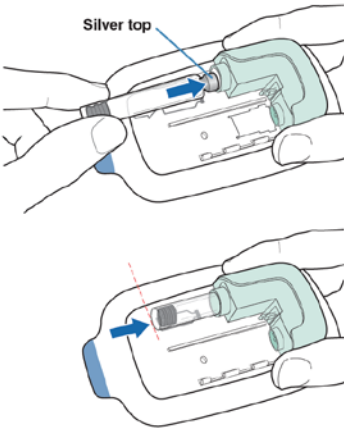
Do not use the Prefilled Cartridge **if the medicine is cloudy, appears yellow-brown, or you see floating particles.**



Step 8

Wipe the silver top of the Prefilled Cartridge with an alcohol pad.

2 Prepare the Medicine (continued)

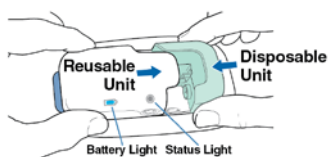


Step 9

Push the **Prefilled Cartridge** into the green Disposable Unit with the silver top inserted first.

The Prefilled Cartridge is fully inserted when the bottom of the Prefilled Cartridge is at the tip of the arrow on the Disposable Unit.

2 Prepare the Lasix ONYU Infusor



Step 10

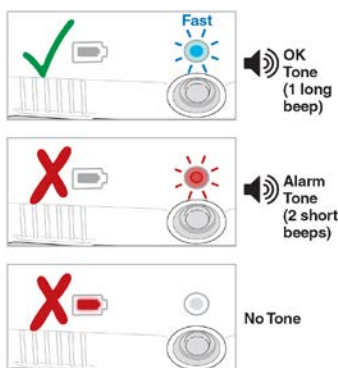
Check the following:

- The Reusable Unit Battery Light is solid blue, and
- The Charger is disconnected from the Reusable Unit.

Slide together the white Reusable Unit and green Disposable Unit together until the Status Light on the Reusable Unit turns on.

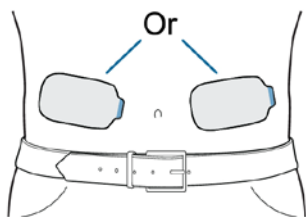
Step 11

Check the Status Light.



- If the **Status Light** is **blue and flashing fast**, and you hear the **OK Tone (1 long beep)**, continue to **Step 12**. The Lasix ONYU Infusor is ready to start your infusion.
- The Lasix ONYU Infusor will remain ready to start infusion for 7 hours.
- If the **Status Light** is **flashing red** and you hear the **Alarm Tone (2 short beeps)**, do not use the Lasix ONYU Infusor. Go to **Troubleshooting: The Status Light is Flashing Red** for instructions.
- If the **Battery Light** is **solid red**, do not use the Lasix ONYU Infusor. Go to **Troubleshooting: Checking the Reusable Unit Battery** for instructions.

2 Prepare the Application Site



Step 12

Choose a site on the stomach, above the beltline, to the left or right of the belly button.

Trim excessive hair at the site. This will help the Lasix ONYU Infusor stick to the skin.

Alternate (rotate) sites between left and right sides of the stomach with each infusion.

Do not choose a site where:

- the skin is irritated, broken, tender, red, bruised, or hard,
- the skin is wet or sweaty,
- there are folds in the skin when standing up straight, or
- belts, waistbands, or tight clothing may rub against or move the Lasix ONYU Infusor.

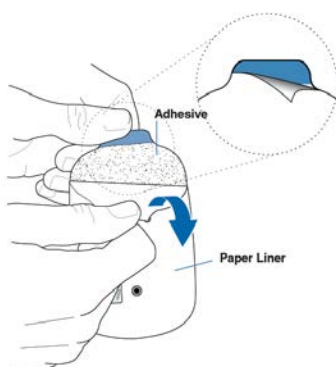


Step 13

Wipe the site with an alcohol pad.

Let dry for at least 10 seconds.

2 Attach the Lasix ONYU Infusor

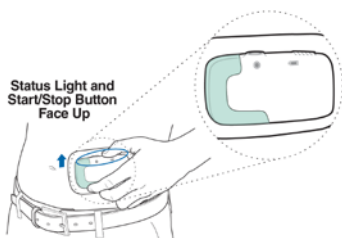


Step 14

Hold the blue tab with one hand and use the other hand to **peel off the paper liner** from the adhesive on the back of the Lasix ONYU Infusor.

Leave the sticky adhesive on the Lasix ONYU Infusor. Only remove the paper liner.

Do not touch the sticky adhesive with your fingers or let it touch any surfaces before sticking the Lasix ONYU Infusor to your stomach.



Step 15

While standing up straight, press the Lasix ONYU Infusor onto the site on your stomach you wiped with the alcohol pad.

Make sure the **Status Light** and the **Start/Stop Button are facing up** in a horizontal position as shown, so you can see them when the Lasix ONYU Infusor is on your stomach.

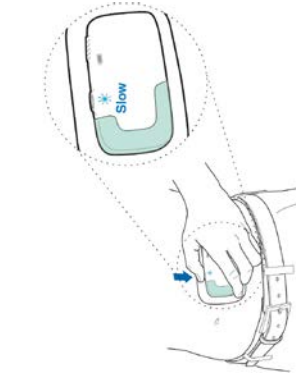


Step 16

Rub the edges of the adhesive with a finger to get the Lasix ONYU Infusor to stick well.

2 Start the Infusion

Start your infusion within 7 hours of connecting the Reusable Unit and Disposable Unit. If more than 7 hours pass without starting your infusion, the Lasix ONYU Infusor will time out and the infusion cannot be delivered (go to **Troubleshooting: The Status Light is Flashing Red**).



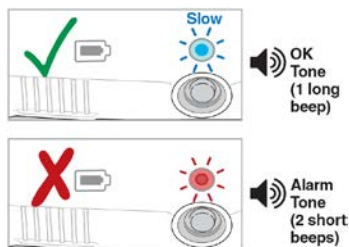
Step 17

Press and hold the Start/Stop Button until you hear the motor and see the blue Status Light change to flashing slow.

The needle will automatically insert into your skin after the Start/Stop Button is pressed. You may feel a slight pinch.

You **will hear the motor start and stop often** during your infusion. The motor runs for a few seconds at a time then pauses for several minutes.

2 Start the Infusion (continued)



Step 18

Check the Status Light.

- If the **Status Light** is **blue and flashing slow**, and you hear the **OK Tone (1 long beep)**, the infusion has **started**. You will hear the motor running.
- If the **Status Light** is **flashing red**, and you hear the **Alarm Tone (2 short beeps)**, the infusion **did not start**. Go to **Troubleshooting: The Status Light is Flashing Red** for instructions.
- If the **Status Light** is **blue and flashing fast**, and you hear the **OK Tone (1 long beep)**, the infusion **did not start**. Repeat **Step 17**.
- For additional assistance go to **Troubleshooting: Lights and Tones Table** for instructions or call 1-855-452-7496.

2 During the Infusion



Wait 5 Hours

Step 19

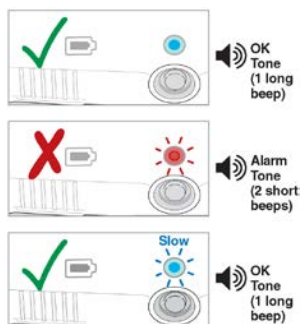
Wait 5 hours for the Lasix ONYU Infusor to deliver the full infusion.

You will see the blue Status Light flashing slow and sometimes hear the motor running.

Check the Lasix ONYU Infusor every now and then to make sure it is working properly.

Do not remove the Lasix ONYU Infusor from your stomach until the infusion is done. The infusion is complete when the Status Light is solid blue and you hear the OK Tone (1 long beep). Go to **Troubleshooting: How to Stop the Infusor Early** if you need to stop the infusion early.

2 End the Infusion

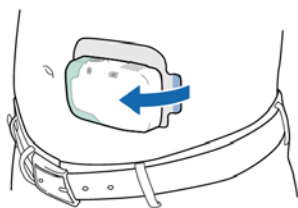


Step 20

After 5 hours, **check** the Status Light.

- If the **Status Light** is **solid blue**, and you hear the **OK Tone (1 long beep)**, the infusion is **done**.
- If the **Status Light** is **flashing red**, and you hear the **Alarm Tone (2 short beeps)**, an error happened. Go to **Troubleshooting: The Status Light is Flashing Red**.
- If the **Status Light** is **blue** and **flashing slow**, and you hear the **OK Tone (1 long beep)**, the infusion is **not done yet**. Continue to wait.

The **needle automatically pulls in (retracts)** when the infusion is done. You may feel a slight pinch.

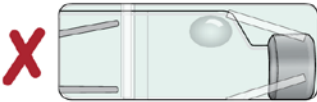
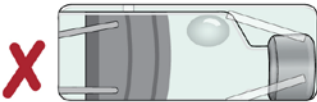
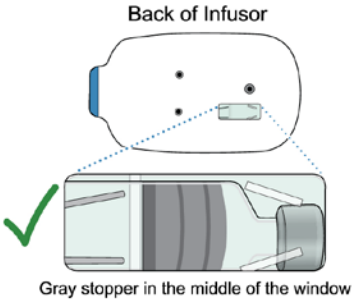


Step 21

When the infusion is done, **remove the Lasix ONYU Infusor** from your stomach. Peel the Lasix ONYU Infusor off the skin by holding down the skin and pulling the blue tab away from the stomach.

You might have some discomfort after you remove the Lasix ONYU Infusor. This discomfort should quickly go away, but some redness of the skin may remain. If there is any bleeding, pat with a small cotton ball or apply a small adhesive bandage over the site.

2 Confirm the Infusion Worked



Step 22

Look in the window on the back of the Lasix ONYU Infusor to check whether all the medicine was delivered.

- If the middle of the window is all **gray** (whole gray stopper is visible with very little or no liquid), all of the medicine was delivered.
- If you **see anything else** (like a lot of liquid, a large bubble in the liquid, no gray stopper, or only part of the gray stopper), some of the medicine was not delivered. **Call your healthcare provider right away.**

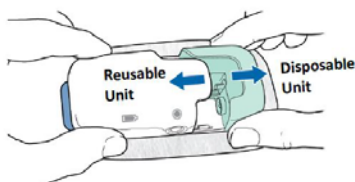


Step 23

Confirm the medicine worked.

- If you **urinate a lot** (at least 2 times during the 5-hour infusion), the **medicine worked**.
- If you **urinate less than 2 times** (during the 5-hour infusion), the medicine may not have worked. **Call your healthcare provider right away.**

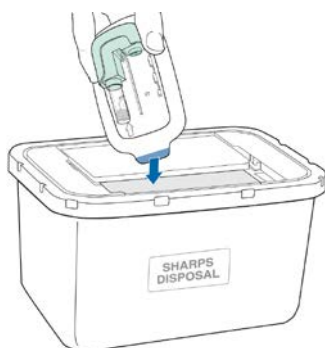
2 Throw Away (Disposal), Cleaning, and Storage



Step 24

Pull apart the green Disposable Unit and white Reusable Unit.

The Reusable Unit automatically turns off when the two parts are separated.



Step 25

Do not save and re-use the green Disposable Unit or Prefilled Cartridge. **They are for one-time use only.**

Throw away the green Disposable Unit into an FDA-cleared **sharps disposal container**.

You may obtain a free sharps disposal container from SQ Innovation. Visit www.sqinnovation.com/sharps/ or call 1-855-452-7496 to have a container mailed to you at no charge. Alternatively, if you do not have an FDA-cleared sharps disposal container, you may use a household container that is:

- made of heavy-duty plastic,
- can be closed with a tight fitting, puncture-resistant lid, without sharps being able to come out,
- upright and stable during use,
- leak-resistant, and
- properly labeled to warn of hazardous waste inside the container.

2 Throw Away (Disposal), Cleaning, and Storage (continued)

When your Sharps container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you throw away used needles and syringes. For more information about safe sharps disposal and for specific information about sharps disposal in the state that you live in, go to the FDAs website at:

<https://www.fda.gov/medical-devices/safely-using-sharps-needles-and-syringes-home-work-and-travel/best-way-get-rid-used-needles-and-other-sharps>

Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this.

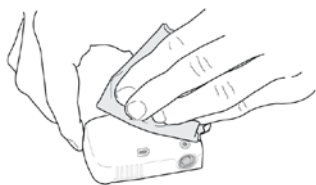
Do not recycle the green Disposable Unit and used sharps disposal container or throw them away into household trash.

Important: Always keep the sharps disposal container out of the reach of children.

Scan the code below with your phone for a sharps disposal location near you or call Safe Needle Disposal at 1-800-643-1643.



2 Throw Away (Disposal), Cleaning, and Storage (continued)



Do not use harsh cleaners that contain bleach, alcohol, ammonia, or other solvents. These cleaners may damage the Reusable Unit.

Do not submerge the Reusable Unit **in liquids** or spray liquids directly on the surface. It contains parts that should not get wet.

Step 26

Wipe the white Reusable Unit with a clean, water-damp cloth to remove visible dirt right after use. Let dry completely before storing.

If needed, a mild detergent, like dish soap, may be added to the damp cleaning cloth.

Step 27

Store the Reusable Unit, Charger, and any remaining Lasix ONYU Kits for next use.

- Keep at room temperature between 68°F and 77°F (20°C and 25°C).
- **Do not** refrigerate or freeze.
- Keep in a dark place to protect from light.
- Keep dry.
- Keep extra Prefilled Cartridges and Disposable Units in their original packaging until it is time to use them.



Chapter 3

Troubleshooting

3 Customer Service Contact Information

Contact Information:

SQ Innovation, Inc.
Burlington, MA 01803, USA

Phone: 1-855-452-7496 (1-855-4LASIX6)

www.Lasix-ONYU.com

3 Lights and Tones Table

Lights		Tones	What it Means
Battery Light Flashes Blue		No Tone	Battery is charging.
Battery Light Solid Blue		No Tone	Battery is charged and ready for use.
Battery Light Solid Red		No Tone	Low battery. Reusable Unit must be charged before use.
Battery Light and Status Light Solid Red		No Tone	Reusable Unit has expired and must be replaced.
Status Light Blue and Flashes Fast		Ok Tone (1 long beep)	Infusor is ready for medicine delivery.
Status Light Blue and Flashes Slow		Ok Tone (1 long beep)	Infusor is delivering medicine.
Status Light Solid Blue		Ok Tone (1 long beep)	Delivery of medicine is done.
Status Light Flashes Red		Alarm Tone (2 short beeps)	1. Device or delivery cycle error. 2. Delivery of medicine stopped by user.

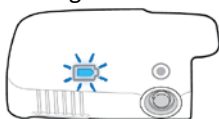
3 Checking the Reusable Unit Battery

If the Battery Light is charged, the white Reusable Unit is able to deliver a full infusion. If the Battery Light is low, the Reusable Unit cannot deliver a full infusion and it needs to be charged.

Always charge the Reusable Unit before you use a new Disposable Unit (before each infusion).

Charging may take up to 20 minutes.

-
- A. Battery Light is flashing blue



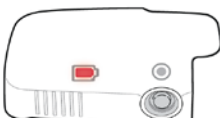
The Reusable Unit **battery is being charged**. Wait until the Battery Light turns solid blue before using the Lasix ONYU Infusor.

-
- B. Battery Light is solid blue



The Reusable Unit **battery is done charging** and ready to use.

-
- C. Battery Light is solid red **before preparing the Lasix ONYU Infusor for use**



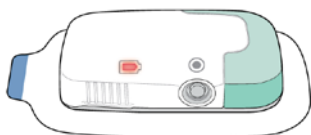
The Reusable Unit **battery is low** and cannot deliver a full infusion.

Charge the Reusable Unit:

1. Plug the Charger into the back of the Reusable Unit.
2. Plug the other end of the Charger into a power outlet.
3. Wait until the Battery Light turns solid blue.

3 Checking the Reusable Unit Battery (continued)

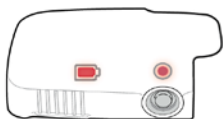
- D. Battery Light is solid red **when the Disposable Unit and Reusable Unit are connected**



The Reusable Unit **battery is low** and the Lasix ONYU Infusor will not start.

1. Pull apart the white Reusable Unit and green Disposable Unit.
2. Put the Disposable Unit to the side while you charge the Reusable Unit (**do not** remove the Prefilled Cartridge from the Disposable Unit).
3. Charge the Reusable Unit:
 - a. Plug the Charger into the back of the Reusable Unit.
 - b. Plug the other end of the Charger into a power outlet.
 - c. Wait until the Battery Light turns solid blue.
 - d. Follow instructions beginning with **Step 10 in Prepare the Lasix ONYU Infusor** to connect the Reusable Unit to the Disposable Unit.

3 The Reusable Unit Has Expired



When the Reusable Unit expires, the Lasix ONYU Infusor can no longer be used. The Reusable Unit needs to be replaced.

The Reusable Unit is expired if it does not light up at all after charging or the **Status Light and the Battery Light are both solid red** when the Reusable Unit is plugged in or when the Reusable Unit and Disposable Unit are pulled apart.

Call 1-855-452-7496 for a replacement Reusable Unit, which will be shipped overnight when possible. Also call your healthcare provider.

The Reusable Unit should not be thrown away (disposed of) with household waste and should not be recycled in your local recycling program. Throw away the Reusable Unit according to local regulations for electronic devices with lithium batteries.

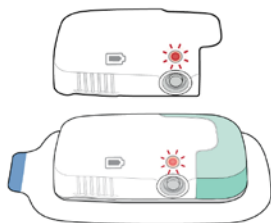
Alternatively, the Reusable Unit may be returned to SQ Innovation, free of charge, for proper and safe recycling. Go to **Chapter 4** for more information.

3 The Status Light is Flashing Red

When an **error happens inside the Lasix ONYU Infusor** or the white Reusable Unit and green Disposable Unit have been **connected for 7 hours without starting the infusion**, the Status Light will flash red and you will hear a repeating Alarm Tone (2 short beeps).

This can happen in the following 2 situations:

- **Before** the white Reusable Unit and green Disposable Unit are **connected**, see Section A below for what to do.
- **After** the white Reusable Unit and green Disposable Unit are **connected**, see Section B below for what to do.



Or



A. If the Status Light flashes red **before** the white Reusable Unit is **connected** to the green Disposable Unit, **a device error happened**. Follow the instructions below:

1. Unplug the Charger (if it is connected).
2. Press and hold the Start/Stop Button until the flashing red light turns off (1 second).
3. Plug the charger into the Reusable Unit and a power outlet. Check the Lights:

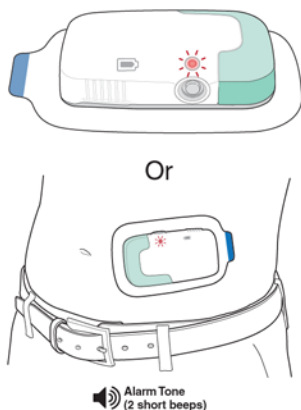


 Alarm Tone (2 short beeps)

- If the **Battery Light** is **solid** or **flashing blue**, the Reusable Unit is **ready to use**. Continue with **Step 2 in Get Ready for the Infusion**.
- If the **Status Light** is still **flashing red**, the Reusable Unit cannot be used. Call 1-855-452-7496 for a replacement Reusable Unit, which will be shipped overnight when possible. Also call your healthcare provider.

3 The Status Light is Flashing Red (continued)

- B.** If the Status Light flashes red **after connecting** the white Reusable Unit and green Disposable Unit, **a device error happened** or the **Lasix ONYU Infusor timed out** (because it was connected for 7 hours without starting the infusion). The Lasix ONYU Infusor cannot be used. Follow the steps below:



1. If the Lasix ONYU Infusor is on the body, **remove it from** the stomach.
2. If you can see the needle, **do not touch the needle** because you could get an injury.
3. **Pull apart** the Reusable Unit and Disposable Unit.
4. **Throw away the Disposable Unit** with the Prefilled Cartridge **into an FDA-cleared sharps disposal container** (see **Step 25 in Throw Away (Disposal), Cleaning and Storage**). You should not throw away the Disposable Unit in the household trash.
 - **Do not** save and re-use the Disposable Unit or Prefilled Cartridge as the medicine may be contaminated. They are for one-time use only.
5. Determine the next steps:
 - a. If the error happened **before the infusion was started**, get a new Lasix ONYU Kit and **start over at Step 1 in Get Ready for the Infusion**.
 - b. If the error happened **after the infusion was started**, **call your healthcare provider** to see what to do because some of the medicine was not delivered.

3 You Can See the Needle

You may see the needle in one of these situations:

- You **press the Start/Stop Button before the Lasix ONYU Infusor is placed on the stomach**, see Section A below for what to do.
- You **remove the Lasix ONYU Infusor before infusion is done** or the **Lasix ONYU Infusor falls off** during the 5-hour infusion, see Section B below for what to do.
- The **needle did not retract automatically** after infusion, see Section C below for what to do.

Do not touch the needle because you could get an injury.

- A.** If you see the needle **before the Lasix ONYU Infusor is placed on the stomach**, you should start over with a new Lasix ONYU Kit. Follow the steps below:
1. **Press and hold the Start/Stop Button** (4 seconds) until the Status Light flashes red and you hear the Alarm Tone (2 short beeps).
 2. **Pull apart** the white Reusable Unit and green Disposable Unit.
 3. **Throw away the Disposable Unit** with the Prefilled Cartridge **into an FDA-cleared sharps disposal container**. You should not throw away the Disposable Unit in the household trash.
 - **Do not** save and re-use the Disposable Unit or Prefilled Cartridge as the medicine may be contaminated. They are for one-time use only.
 4. **Return to Step 1 in Get Ready for the Infusion** to start over with a new Lasix ONYU Kit. Be careful not to press the Start/Stop Button until after the Lasix ONYU Infusor is on the stomach.

3 You Can See the Needle (continued)

- B.** If you see the needle because **the Lasix ONYU Infusor fell off or it was removed before infusion was done**, follow the steps below:

You should not stick the Infusor back on the stomach because it may fall off again.

1. **Press and hold the Start/Stop Button** (4 seconds) until the Status Light flashes red and you hear the Alarm Tone (2 short beeps).
 2. **Pull apart** the white Reusable Unit and green Disposable Unit.
 3. **Throw away the Disposable Unit** with the Prefilled Cartridge **into an FDA-cleared sharps disposal container**. You should not throw away the Disposable Unit in the household trash.
 - **Do not** save and re-use the Disposable Unit or Prefilled Cartridge as the medicine may be contaminated. They are for one-time use only.
 4. **Call your healthcare provider** to see what to do because some of the medicine was not delivered.
-

- C.** If you see the needle **after the 5-hour infusion is done**, the needle did not retract automatically. Follow the steps below:

1. **Carefully pull apart** the white Reusable Unit and green Disposable Unit.
 2. **Throw away the Disposable Unit** with the Prefilled Cartridge **into an FDA-cleared sharps disposal container**. You should not throw away the Disposable Unit in the household trash.
 - **Do not** save and re-use the Disposable Unit or Prefilled Cartridge as the medicine may be contaminated. They are for one-time use only.
 3. **Continue with Step 26 and Step 27 in Throw Away (Disposal), Cleaning, and Storage** to clean and store the Reusable Unit.
-

3 How to Stop the Lasix ONYU Infusor Early

Follow these steps below if you need to stop the Lasix ONYU Infusor before the 5-hour infusion is finished. **Do not remove the Lasix ONYU Infusor** from the stomach **before stopping it**. Removing the Lasix ONYU Infusor from the body before stopping it will expose the needle, and you could get an injury if you touch it.



1. **Press and hold the Start/Stop Button** (4 seconds) until you hear the Alarm Tone (2 short beeps) and the Status Light is flashing red.



Alarm
Tone
(2 short
beeps)



2. **Confirm** infusion was stopped. Check the Status Light:
 - If the **Status Light** is **flashing red** and you hear the Alarm Tone (2 short beeps), the infusion has **stopped**. The needle will retract shortly after you press the Start/Stop Button.
 - If the **Status Light** is **blue and flashing slow**, the infusion **did not stop**. Repeat **Step 1** in **How to Stop the Lasix ONYU Infusor Early** above.

3. The infusion cannot be restarted. You must **remove the Lasix ONYU Infusor** and contact your healthcare provider. Follow the steps below:
 - a. **Remove** the Lasix ONYU Infusor from your stomach.
 - b. **Pull apart** the white Reusable Unit and green Disposable Unit.
 - c. **Throw away the Disposable Unit** with the Prefilled Cartridge in an **FDA-cleared sharps disposal container**. You should not throw away the Disposable Unit in the household trash.
 - **Do not** save and re-use the Disposable Unit or Prefilled Cartridge as the medicine may be contaminated. They are for one-time use only.
 - **Call your healthcare provider** because you did not get all of the medicine.

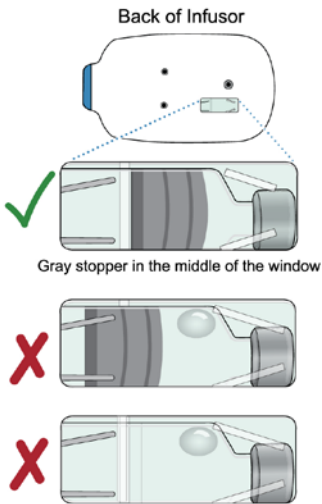
3 You Did Not Urinate (Pee) Much During the Infusion

The Lasix ONYU Infusor delivers a diuretic medicine which should make you urinate a lot. If you do not urinate a lot (at least 2 times during the 5-hour infusion), there are two reasons this could have happened:

- The diuretic medicine, Lasix ONYU, was not effective for you, or
- The Lasix ONYU Infusor did not work properly.



In either case, **it is important that you call your healthcare provider.** Follow the steps below to determine whether the Lasix ONYU Infusor worked and if all the medicine was delivered:



1. **Remove the Lasix ONYU Infusor** from your stomach.

2. **Look at the window** on the back of the Lasix ONYU Infusor:

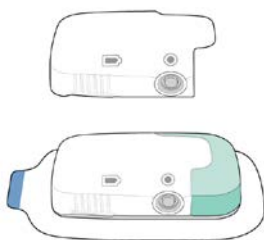
- If the middle of the window is all **gray** (whole gray stopper is visible with very little or no liquid), all the medicine was delivered. The Lasix ONYU Infusor worked.
- If you **see anything else** (like a lot of liquid, a large bubble in the liquid, no gray stopper, or only part of the gray stopper), some of the medicine was not delivered. You did not get a full infusion.

3. **Check your stomach:** If you see or feel a lot of liquid on your stomach, you may not have received a full infusion due to the medicine leaking.

3 The Reusable Unit Does Not Light Up

This can happen in the following situations:

- The **Reusable Unit has not been used for a long time** or the **Reusable Unit is expired**, see Section A below for what to do.
- The **Reusable Unit and Disposable Unit have been connected for more than 7 hours** and the infusion has not been started, see Section B below for what to do.

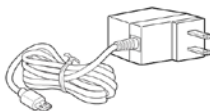


A. If the white **Reusable Unit does not light up**, try charging it, even if it has recently been charged. The Battery Light on the Reusable Unit must always be solid blue before connecting it to the Disposable Unit. Follow the steps below:

1. **Plug** the Charger into the back of the Reusable Unit and plug the other end of the Charger into a power outlet.
2. **Wait** 20 minutes.
3. **Disconnect** the Charger from the Reusable Unit and power outlet.
4. **Check** the Battery Light:



- If the **Battery Light is solid blue**, the Reusable Unit is **ready to use**.
- If the **Battery Light did not light up** after 20 minutes of charging, the Reusable Unit expired. Call 1-855-452-7496 for a replacement Reusable Unit, which will be shipped overnight when possible. **Also call your healthcare provider.**



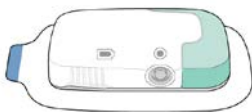
Go to **Troubleshooting: The Reusable Unit Has Expired** for more information.

- If you see other lights, go to **Troubleshooting: Lights and Tones Table**.

3 The Reusable Unit Does Not Light Up (continued)

- B.** If the **Reusable Unit and Disposable Unit have been connected for more than 7 hours** and the infusion has not been started, the Lasix ONYU Infusor will automatically time out. The Lasix ONYU Infusor cannot be restarted. Follow the steps below:

1. If the Lasix ONYU Infusor is on the body, **remove the Lasix ONYU Infusor** from your stomach.
2. If you can see the needle, **do not touch the needle** because you could get an injury.
3. **Pull apart** the Reusable Unit and Disposable Unit.
4. **Throw away the Disposable Unit** with the Prefilled Cartridge in an **FDA-cleared sharps disposal container**. You should not throw away the Disposable Unit in the household trash.
 - **Do not** save and re-use the Disposable Unit or Prefilled Cartridge as the medicine may be contaminated. They are for one-time use only.
5. Get a new Lasix ONYU Kit and **start over** at **Step 1 in Get Ready for the Infusion**.



3 The Lasix ONYU Infusor Will Not Start the Infusion

You press the Start/Stop Button and the infusion does not start.

This can happen in the following situations:

- The **Reusable Unit and Disposable Unit are not properly connected**, see Section A below for what to do.
- The **Reusable Unit is powered off** and both the Battery Light and Status Light are off, go to **Troubleshooting: The Reusable Unit Does Not Light Up** for what to do.
- A **device error has happened** and the Status Light is flashing red, go to **Troubleshooting: The Status Light is Flashing Red** for what to do.

A. If the infusion does not start, follow the steps below:

1. **Firmly push** the Reusable Unit and Disposable Unit **together**. There should be no gap or space between the parts when they are properly connected.
2. Check the Status Light:
 - If the **Status Light** is **blue** and **flashing fast** and you hear the OK Tone (1 long beep), the Lasix ONYU Infusor is properly connected. The **Lasix ONYU Infusor is ready** to deliver the infusion.

If the Lasix ONYU Infusor is **not on the body**, go to **Step 12** in **Prepare the Application site**.

If the Lasix ONYU Infusor is **on the body**, go to **Step 17** in **Start the infusion**.

- If the **Status Light** is **flashing red** and you hear the Alarm Tone (2 short beeps), there is a **problem with the Infusor**. Go to **Troubleshooting: The Status Light is Flashing Red** to see what to do.



 **OK Tone**
(1 long beep)



 **Alarm Tone**
(2 short beeps)

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Issued: ##/202#

Chapter 4

Technical Information

4 Part Numbers

Part Number	Description	Materials Included
CP-FK-001	Lasix ONYU Starter Kit	Three (3) Lasix ONYU Kits One (1) Reusable Unit One (1) Charger Instructions for Use
CP-FK-002	Lasix ONYU Kit*	One (1) Disposable Unit One (1) Single-Dose Prefilled Cartridge Two (2) Alcohol Pads Prescribing Information
CP-FK-003	Reusable Unit and Charger Box	One (1) Reusable Unit One (1) Charger Instructions for Use

*** Materials of the Lasix ONYU Kit are not sold separately.**

4 Specifications

Item	Specification
Number of Uses	Disposable Unit: single use Reusable Unit: (including power supply) 2 years/ 48 uses.
Ingress Protection	Reusable Unit: IP42 (protection against water dripping (15° tilted), protection against solid foreign objects $\geq 1.0\text{mm}$ diameter)
EIRP (Equivalent Isotropic Radiated Power)	Reusable Unit: 3.5 dBm
Alarm type	Reusable Unit: Audible (piezo buzzer)
Drug dosage	80 mg over 5 hrs (30 mg in the first hour and 12.5 mg/hr over the next 4 hours)
Fill volume of Prefilled Cartridge	2.75-2.95 mL
Needle	Disposable Unit: Surgical Steel (36L), 29 Ga. Insertion depth 4-8mm
Operating temperature range	All Components: 5°C to 40°C (41°F to 104°F)
Transport/Storage temperature range	Device Components: -25°C to 55°C (-13°F to 131°F) Recommended storage: 68°F to 77°F (20°C to 25°C)
Operating humidity range	All Components: 15% to 90%, non-condensing
Transport/Storage humidity range	All Components: 0% to 90%, non-condensing
Operating, Transport and Storage atmospheric pressure range	All Components: 700 to 1,060 hPa

4 Specifications (continued)

Item	Specification
Operating and storage atmospheric pressure	All Components: 700 - 1,060 hPa
Non-pyrogenic	Disposable Unit: fluid pathway only
Delivery Speed	1 mL over the first hour and ~0.42 mL/hr over the next 4 hours
Reusable Unit Dimensions	(L) 78 mm x (W) 49 mm x (H) 21 mm
Reusable Unit Weight	38 g
Power Supply	Mfg.: FRIWO Gerätebau GmbH Model: FW8002/05 Input. 100-240 Vac; 50-60 Hz; 160-80 mA, Class II Output: 5.0V, 1400 mA
Battery	Capacity: 120 mAh; 3.8 V The internal battery of the Reusable Unit cannot be removed or replaced. The Reusable Unit is good for 48 infusions.
Operating Mode	Continuous

California Proposition 65

To the best of the manufacturer’s knowledge, this product is in compliance with Proposition 65, and reasonably anticipated use of this product will not result in exposure to any Proposition 65 chemicals that would require a Proposition 65 warning.

4 Symbols

Symbol	Meaning	Explanation
	Warning	Safety hazard indicated

Symbol	Meaning
	Prescription use only
	Refer to Instructions for Use
	Do not use if the package is damaged
	Keep dry
	Magnetic Resonance (MR) unsafe
	Type body floating (BF) applied part (Patch)
	Alternating Current (AC – power supply only)

Symbol	Meaning
	Manufacturer
	Date of Manufacture
	Warning
	Serial Number
	IP Code
	Sterilized using gamma radiation (DU)
	Single patient, multiple use (Reusable Unit only)

4 Symbols (continued)

Symbol	Meaning	Symbol	Meaning
	Temperature Range		Direct Current (DC – power supply only)
	Product reference or part number		Battery Light (Reusable Unit only)
	Waste batteries and accumulators		Drug Cartridge (Disposable Unit only)
	Status Light (Reusable Unit only)		USB Port Symbol (Reusable Unit only)
	Class II Equipment (Power Supply only)		Do not reuse

Information on disposal of electrical and electronic equipment and disposal of batteries and accumulators:

The crossed out wheeled bin symbol with under bar shown on the product or accompanying documents indicates the product requires appropriate treatment, collection and recycle for waste electrical and electronic equipment (WEEE) under the Directive 2012/19/EU:



This product should not be disposed of as unsorted household waste.

- The Reusable Unit should be disposed of according to local regulations for electronic equipment with lithium batteries or call-1-855-452-7496 for instructions on how to recycle the Reusable Unit safely (free program). Do not recycle in local recycling programs.
- The Charger should be disposed of according to local regulations for electronic equipment or through a community electronics recycling center.

4 EMC Safety

Guidance and manufacturer's declaration - electromagnetic emissions

The Infusor is intended for use in an electromagnetic environment as specified below. The customer or the user of the Product should ensure that it is used in such an environment.

Emissions test	Test level/ requirement	Electromagnetic environment guidance
Radiated disturbance CISPR 11:2015	Group 1 Class B	<i>The Infusor utilizes no intention RF fields.</i> Therefore, its RF emissions are very low and are not likely to cause any interference to nearby electronic equipment.
Mains terminal disturbance voltage CISPR 11:2015	Group 1 Class B	
Harmonics Current Emission IEC 61000-3-2:2014	Class A	<i>Infusor</i> is suitable for use in all establishments, including clinical and domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Voltage change, Voltage fluctuations and Flicker Emission IEC 61000-3-3:2013	Pst:1dmax: 4%	

4 EMC Safety (continued)

Guidance and Manufacturer’s Declaration - Electromagnetic Immunity

Infusor is intended for use in the electromagnetic environment specified below. The customer or the user of the **Infusor** should assure that it is used in such an environment.

Immunity test	Operating Mode	Supply Voltage	Test level/ requirement	Electromagnetic environment guidance
Electrostatic Discharge Immunity IEC 61000-4-2:2008	Furosemide injection/ Charging mode & Battery operating	120V, 60Hz d.c.3.7V	±8kV/Contact ±2, ±4, ±8 ± 15kV/Air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF Electromagnetic Field immunity IEC 61000-4-3:2010	Furosemide injection/ Charging mode & Battery operating	120V, 60Hz d.c.3.7V	10 V/m 80 MHz-2.7 GHz 80% AM at 1 kHz	Infusor is suitable to use in home and healthcare environment

4 EMC Safety (continued)

Immunity test	Operating Mode	Test Voltage	Test level/ requirement	Electromagnetic environment guidance
Immunity to Proximity Fields from RF wireless Communications Equipment IEC 61000-4-3:2010	Furosemide injection/ Charging mode & Battery operating	120V, 60Hz d.c.3.7V	A1) 380 MHz –18Hz PM (Pulse Modulation) A2) 450 MHz –18Hz PM @ 50% A3) 710, 745 & 780MHz – 18 Hz PM A4) 810, 870 & 930MHz – 18Hz PM A5) 1720, 1845, 1970 & 2450 MHz – 18 Hz PM A6) 5240, 5500 & 5785MHz – 18 Hz PM	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Infusor , including cables specified by SQ Innovation. Otherwise, degradation of the performance of this equipment could result
Electrical Fast Transient/ Burst Immunity IEC 61000-4-4:2012	Furosemide injection/ Charging mode	120V, 60Hz	± 2 kV, 100kHz repetition frequency	The quality of supplied power be suitable for home healthcare environment.
Surge Immunity IEC 61000-4-5:2014	Furosemide injection/ Charging mode	120V, 60Hz	Line to Line ±0.5kV, ±1kV	The quality of supplied power be suitable for home healthcare environment.

4 EMC Safety (continued)

Immunity test	Operating Mode	Test Voltage	Test level/ requirement	Electromagnetic environment guidance
Power Frequency Magnetic Field Immunity IEC 61000-4-8:2009	Furosemide injection/ Charging mode & Battery operating	120V, 60Hz d.c.3.7V	30 A/m 50 Hz & 60Hz	If degradation of the primary performance occurs, it may be necessary to position the Infusor further from sources of power frequency magnetic fields.
Immunity to Conducted Disturbances induced by RF fields IEC 61000-4-6:2013	Furosemide injection/ Charging mode	120V, 60Hz	3 V 0.15-80 MHz 6 V in ISM bands & Amateur radio bands between 0.15 and 80 MHz 80% AM at 1kHz	The strength of RF field in the frequency range 150 kHz~80 MHz, the strength of the RF field should be smaller than 3 V. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Infusor

4 EMC Safety (continued)

Immunity test	Operating Mode	Test Voltage	Test level/ requirement	Electromagnetic environment guidance
Voltage dips, IEC 61000-4-11:2004	Furosemide injection/ Charging mode	100V, 60Hz 240V, 50Hz	0 % UT: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 Cycles Single phase: at 0°	The quality of supplied power should be suitable for home healthcare environment. For the user to operate the equipment continuously even the electric power supply is interrupted, it is recommended that the uninterruptable power supply device (UPS) or battery is prepared.
Voltage interruption IEC 61000-4-11:2004	Furosemide injection/ Charging mode	100V, 60Hz 240V, 50Hz	0% UT; 250/300 cycle	The quality of supplied power should be suitable for home healthcare environment. For the user to operate the equipment continuously even the electric power supply is interrupted, it is recommended that the uninterruptable power supply device (UPS) or battery is prepared.

4 EMC Safety (continued)

Immunity test	Operating Mode	Test Voltage	Test level/ requirement	Electromagnetic environment guidance
Immunity to Proximity Magnetic Field - AIM 7351731 and IEC 61000-4-39	Furosemide injection/ Charging mode & Battery operating	120V, 60Hz d.c.3.7V	30 kHz, CW, 8 A/m 134.2 kHz, pulse modulation 2.1 kHz, 65 A/m rms 13.56 MHz, pulse modulation 50 kHz, 7.5 A/m rms	If degradation of the primary performance occurs, it may be necessary to position the Infusor further from sources of magnetic fields.

4 EMC Safety (continued)

The Infusor uses no RF communication thus the potential for disturbance is low but may exist, even with equipment that complies with FCC and CISPR emissions requirements.

The Infusor complies with the immunity requirements of the general standard for electromagnetic compatibility, IEC 60601-1-2.

The Infusor complies with Canadian ICES-003 and IC-RSS-210 as well as FCC regulations on medical device emissions.

The Infusor complies with all relevant sections of IEC 60601-1:2005+AMD1:2012+AMD2:2020 for electrical safety.

The Infusor complies with relevant provisions of IEC 60601-2-24 for flow accuracy and performance. The Infusor is rated for 2.67 ml +/- 10% delivery over 5 hours.

Primary Performance:

Primary Performance of the Lasix ONYU Infusor is: Deliver Lasix ONYU to the patient per specification when operating normally (continuous accurate delivery).

Warning: Use of the Infusor adjacent to other electrical or magnetic equipment should be avoided because it could result in improper operation. If such use is necessary, the Infusor and the other equipment should be observed to verify that they are operating normally.

Warning: Portable RF communications equipment (including cell phones, antenna cables, antennas) should be used no closer than 12 inches (30 cm) to the Infusor. Otherwise, Infusor performance could be degraded.

Warning: Use of a charger other than the one specified or provided by the manufacturer of the Infusor could result in increased electromagnetic emissions or decreased electromagnetic immunity of the Infusor and result in improper operation.

Warning: The Infusor contains NO serviceable parts or modifiable parts. Do not attempt to service or modify the device.

Chapter 5

Additional Information

5 Watch Training Video

Scan the code below with your phone to see the training video
or visit the website: www.Lasix-ONYU.com/infusor-training



5 Warranty Information

Limited Warranty

SQ Innovation, Inc. (SQI) warrants that the Reusable Unit of the Infusor for Lasix® ONYU will be free from defects in materials and workmanship for a period of two years from the date of manufacture or 48 uses, whichever occurs first (the “Warranty Period”). Warranty claims must be made in writing to SQI within the Warranty Period. Buyer’s sole and exclusive remedy (and SQI’s sole and exclusive liability) for any warranty claim is replacement or refund of purchase price, at SQI’s option. Such remedies shall not extend the warranty period.

This warranty is valid only if the Reusable Unit is used in accordance with SQI’s Instructions for Use for the labeled indications. It does not apply in event of:

- modifications by Buyer or a third party;
- use with non-SQI provided materials;
- improper use, including but not limited to abuse, neglect, misuse, or accident, such as improper storage, excessive wear, submersion in water (or any other liquid), or physical abuse such as dropping; or
- *Force Majeure* or other event beyond the control of the manufacturer.

This warranty is personal to the original Buyer and shall terminate upon transfer to or use by a user other than the original Buyer, or use outside the country of purchase. This warranty does not apply to other components, such as Prefilled Cartridges, Disposable Units or accessories. NEITHER SQI NOR ITS SUPPLIERS OR DISTRIBUTORS SHALL BE LIABLE FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, OR SPECIAL DAMAGES OR LOST PROFITS ARISING OUT OF A DEFECT, WHETHER BASED ON TORT, WARRANTY, CONTRACT OR OTHERWISE.

All other warranties, expressed or implied, are disclaimed, including the warranties of merchantability and fitness for a particular purpose. To the extent such disclaimers are not allowed by applicable law, any implied warranties are limited to the duration of the express warranty. The limited duration of implied warranty and limitation of indirect damages do not apply where prohibited by applicable law.

* Legal Notice

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