HIGHLIGHTS OF PRESCRIBING INFORMATION

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

Lumitrace (relmapirazin) 18.6 mg/mL injection, for intravenous use

Initial US Approval: 2025 Rx only

----------RECENT MAJOR CHANGES----------

N/A

----------INDICATIONS AND USAGE----------

The MediBeacon® Transdermal GFR System (TGFR) is intended to assess the Glomerular Filtration Rate (GFR) in adult patients with impaired or normal renal function by noninvasively monitoring fluorescent light emission from an exogenous tracer agent over time. This device has been validated in patients with stable renal function.

The MediBeacon® TGFR is not approved for use in patients with GFR <15 ml/min/1.73 m², GFR >120 ml/min/1.73m², patients on dialysis, or anuric patients. The use of this device in patients with dynamic and rapidly changing renal function has not been validated. This device is not intended to diagnose acute kidney injury (AKI).

The MediBeacon® TGFR Disposable Ring and the exogenous tracer agent, Lumitrace® injection, are single use and are only used with the MediBeacon® TGFR.

The MediBeacon® TGFR Disposable Ring is intended to be assembled with the MediBeacon® TGFR Reusable Sensor and attaches to the patient's skin during a TGFR session.

The MediBeacon® TGFR Reusable Sensor is intended to excite fluorescence in Lumitrace® injection, the tracer agent, and measure the returning light intensity. The data is sent to the MediBeacon® TGFR Monitor.

Lumitrace® is an injectable exogenous fluorescent tracer indicated for use with the MediBeacon® Transdermal GFR System (TGFR) for Glomerular Filtration Rate assessment.

----------DOSAGE AND ADMINISTRATION----------

Extravasation: Closely monitor the infusion site for extravasation and infiltration. (2.1)

The adult dose is 7 mL injection via direct intravenous (IV) injection over 30-60 seconds. (2.3)

DOSAGE FORMS AND STRENGTHS

Dosage form: 18.6 mg/mL

----------CONTRAINDICATION----------

None.

----------WARNINGS AND PRECAUTIONS----------

- Dosing of Lumitrace should not occur until after the MediBeacon TGFR Sensor is attached to the patient and the Monitor indicates that baseline readings have been obtained.
- Extravasation may prevent an accurate GFR reading
- Lumitrace injection may interfere with clinical laboratory tests. The presence of Lumitrace decreased B-Type Natriuretic Peptide (BNP) results by around 20% in limited testing. DO NOT ADMINISTER if the patient is expected to need clinical laboratory testing while Lumitrace is present in their system (up to 72 hours for renally impaired patients).
- Lumitrace® injection has light absorbance at 266 nm and 435 nm, and broad fluorescent emission at ~560 nm when excited at ~440 nm. There is potential interference for clinical chemistry assays that utilize wavelengths near these values. Any drug activated at these wavelengths should not be used in conjunction with Lumitrace.

----------ADVERSE EVENTS----------

Most common adverse reactions (incidence ≥ 1%) are injection site extravasation (2%), headache (1%), hypertension (1%), and ecchymosis (1%).

To report SUSPECTED ADVERSE REACTIONS, contact MediBeacon at 314-269-5808 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------

- Interference due to other fluorescent and photosensitizing drugs (8)

----------USE IN SPECIFIC POPULATIONS----------

- Lactation: Advise not to breastfeed for 24 hours.

See 17 for PATIENT COUNSELING INFORMATION

Revised: 05/2026

Contents

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Lumitrace Information

Lumitrace is an injectable exogenous fluorescent tracer agent indicated for use with the MediBeacon® Transdermal GFR System (TGFR) for Glomerular Filtration Rate assessment.

1.2 TGFR Indication For Use

The MediBeacon® Transdermal GFR System (TGFR) is intended to assess the Glomerular Filtration Rate (GFR) in adult patients with impaired or normal renal function by noninvasively monitoring fluorescent light emission from an exogenous tracer agent over time. This device has been validated in patients with stable renal function.

The MediBeacon® TGFR is not approved for use in patients with GFR <15 ml/min/1.73 m², GFR >120 ml/min/1.73m², patients on dialysis, or anuric patients. The use of this device in patients with dynamic and rapidly changing renal function has not been validated. This device is not intended to diagnose acute kidney injury (AKI).

The MediBeacon® TGFR Disposable Ring and the exogenous tracer agent, Lumitrace® injection, are single use and are only used with the MediBeacon® TGFR.

The MediBeacon® TGFR Disposable Ring is intended to be assembled with the MediBeacon® TGFR Reusable Sensor and attaches to the patient's skin during a TGFR session.

The MediBeacon® TGFR Reusable Sensor is intended to excite fluorescence in Lumitrace® injection, the tracer agent, and measure the returning light intensity. The data is sent to the MediBeacon® TGFR Monitor.

Lumitrace® is an injectable exogenous fluorescent tracer indicated for use with the MediBeacon® Transdermal GFR System (TGFR) for Glomerular Filtration Rate assessment.

2 DOSAGE AND ADMINISTRATION

2.1 Important Administrative Instructions

Dosing of Lumitrace should not occur until after the MediBeacon TGFR Sensor is attached to the patient and the Monitor indicates that baseline readings have been obtained. The screen should read “Administer Lumitrace” indicating the system is ready for dosing.

Closely monitor the infusion site for extravasation or tracer agent infiltration during administration. A severe extravasation may prevent the TGFR from detecting the Lumitrace which prevents a GFR assessment.

2.2 Recommended Dosage

The recommended dose is 7 mL administered over 30-60 seconds.

3 DOSAGE FORMS AND STRENGTHS

Injection for intravenous use, 18.6 mg/mL

4 CONTRAINDICATIONS

There are no known contraindications.

5 WARNINGS AND PRECAUTIONS

Dosing of Lumitrace should not occur until after the MediBeacon TGFR Sensor is attached to the patient and the Monitor indicates that baseline readings have been obtained. The screen should read "Administer Lumitrace" indicating the system is ready for dosing.

Severe extravasation may preclude adequate levels of Lumitrace to obtain a transdermal GFR reading.

Lumitrace injection may interfere with clinical laboratory tests. The presence of Lumitrace decreased B-Type Natriuretic Peptide (BNP) results by around 20% in limited testing. DO NOT ADMINISTER if the patient is expected to need clinical laboratory testing while Lumitrace is present in their system (up to 72 hours for renally impaired patients).

Lumitrace® injection has light absorbance at 266 nm and 435 nm, and broad fluorescent emission at ~560 nm when excited at ~440 nm. There is potential interference for clinical chemistry assays that utilize wavelengths near these values. Any drug activated at these wavelengths should not be used in conjunction with Lumitrace.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Adverse Event Type	Events (N) Pilot 2 114 Subjects	Events (N) Pivotal Study (Single use Sensor) 249 Subjects	Events (N) Bridging Study (Reusable Sensor)149 Subjects	Subjects n (%) 512 Subjects
Injection site extravasation	6	3	2	11 (2%)
Headache	1	4	2	7(1%)
Hypertension	0	2	3	5 (1%)
Ecchymosis	0	3	0	3 (1%)

7 DRUG INTERACTIONS

7.1 Interference with laboratory tests

Lumitrace injection may interfere with clinical laboratory tests. The presence of Lumitrace decreased B-Type Natriuretic Peptide (BNP) levels by around 20% in limited testing. DO NOT ADMINISTER if the patient is expected to need clinical laboratory testing while Lumitrace is present in their system (up to 72 hours for renally impaired patients).

7.2 Interference with analytical methods

Lumitrace® injection has light absorbance at 266 nm and 435 nm, and broad fluorescent emission at ~560 nm when excited at ~440 nm. There is potential interference for clinical chemistry assays that utilize wavelengths near these values. Any drug activated at these wavelengths should not be used in conjunction with Lumitrace.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no available data on LUMITRACE use during pregnancy to evaluate for a drug associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. The physiologic changes that occur during pregnancy result in changes to renal function *(see Clinical Considerations)*. In animal studies, no adverse embryofetal developmental effects were seen for LUMITRACE at doses up to 8 times the maximal recommend human dose (MRHD) of 260.4 mg/day based on body surface area *(see Data).*

The background risk of major birth defects and miscarriage for the indicated population 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 clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Clinical Considerations

Disease-associated maternal and/or embryo/fetal risk

The physiologic changes of pregnancy results in decreased vascular resistance, increased renal plasma, and increased glomerular filtration rate during pregnancy.

Data

Animal Data

In pregnant rats and rabbits, no evidence of harm to the fetus was observed following intravenous administration of LUMITRACE at doses up to 225 and 113 mg/kg/day (highest doses tested), respectively, which correspond to approximately 8 times the MRHD of 260.4 mg/day based on body surface area. Animal reproduction studies are not always predictive of human response.

8.3 Lactation

Risk Summary

There are no data on the presence of relmapirazin in human milk, the effects on the breastfed infant or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for LUMITRACE and any potential adverse effects on the breastfed infant from LUMITRACE or from the underlying maternal condition.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

Of the 398 patients who received Lumitrace in the pivotal (single use sensor) and bridging (reusable sensor) clinical studies, 29% were at least 65 years of age and 9% were 75 years or older.

9 ABUSE AND DEPENDENCE

Lumitrace is not a Controlled Substance and unlikely to be abused or cause dependence.

10 OVERDOSAGE

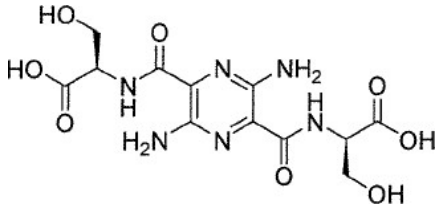
Overdose is unlikely if used as specified with a single 7 mL volume of Lumitrace administered as an intravenous injection.

11 DESCRIPTION

3,6-diamino-2,5-bis{N-[(1R)-1-carboxy-2-hydroxyethyl]carbamoyl}pyrazine, INN name relmapirazin, is a water-soluble fluorescent tracer agent with a molecular weight of 372.3. In a buffered phosphate solution, relmapirazin is totally soluble.

Lumitrace injection is utilized in the MediBeacon Transdermal GFR System. Lumitrace, the TGFR Monitor, TGFR Reusable Sensor, and TGFR Disposable Ring are required to obtain a transdermal GFR reading.

The chemical structure is:

Chemical structure:	
Molecular formula:	$C_{12}H_{16}N_6O_8$

Lumitrace is provided as a sterile, pyrogen-free, clear orangish solution in a single concentration. Each milliliter of Lumitrace injection contains 18.6 mg of relmapirazin with the pH adjusted between 7.0 and 7.6 with hydrochloric acid or sodium hydroxide. All solutions are sterilized by sterile filter and contain no preservatives. Unused portions must be discarded.

Concentration (mg/mL)	Osmolality (mOsm/kg)
18.6	275-350

Lumitrace has osmolarities from approximately 0.9 to 1.2 times that of plasma (285 mOsm/kg water) as shown in the above table.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Relmapirazin is a renal tracer agent that emits fluorescent light that is measured by the optical sensor. It is considered as a renal tracer as it is i) only eliminated by glomerular filtration in the kidney, ii) not protein bound, iii) not metabolized, and iv) does not undergo tubular reabsorption or secretion. Relmapirazin has light absorbance at 266 nm and 435 nm, and broad fluorescent emission at ~560 nm when excited at ~440 nm.

12.3 Pharmacokinetics

The mean maximum plasma concentration (C_{max}) is 12.2 µg/mL following a single intravenous administration.

Distribution

Relmapirazin plasma protein binding is 4.1% based on an in vitro study.

Elimination

The rate of clearance of the tracer agent is characterized by the Renal Decay Time Constant

(RDTC) and is inversely proportional to the patient's GFR. The elimination half-life is 2 hours in subjects with eGFR ≥ 60 mL/min/1.73m^2.

Metabolism

Relmapirazin does not undergo systemic metabolism.

Excretion

Following a single dose administration of relmapirazin greater than 95% of the drug is recovered in urine.

Specific Populations

In all subjects regardless of gender, age, and weight the pharmacokinetic profile followed a two-compartment model for the entire range of subjects studied (15-120 min/mL/1.73m^2). The second compartment of which yields the plasma GFR.

The AUC and Cmax are independent of gender (using a t-test). The Cmax is dependent on weight as expected given a standard dose for all subjects. Subjects with lower GFR tended to be older and hence the AUC was higher in the elderly subjects as expected with lower GFR.

The pivotal (single use sensor) study included a population age range of 19-87, and mix of gender (57% male, 43% female subjects). The bridging (reusable sensor) study included a population age range of 23-82 and a mix of gender (53% male, 47% female subjects).

Renal Impairment

The half-life of relmapirazin is increased to 4 hours in patients with moderate renal impairment (eGFR 30-59 mL/min/1.73m^2) and 8 hours in patients with severe renal impairment (eGFR 15-29 mL/min/1.73m^2). The effect of end stage renal disease receiving dialysis on pharmacokinetics of relmapirazin is unknown.

Drug Interaction Studies

In vitro studies

Cytochrome P450 (CYP) Enzymes: Relmapirazin does not induce or inhibit CYP 1A2, 2C19, 2C9, 2D6 and 3A4.

Transporter systems: Relmapirazin is not a substrate for P-gp, BCRP, MATE1/2K, OAT1 and OCT2, but likely a weak substrate of OAT3. Relmapirazin does not inhibit OCT2, BCRP, MATE1, OAT1/3 and P-gp.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies have been performed to evaluate carcinogenic potential or whether Lumitrace can affect fertility in men or women.

Lumitrace was not mutagenic in Ames test, Chromosomal aberration test, and rat bone marrow micronucleus assay.

14 CLINICAL STUDIES

The main clinical study was a global, multicenter, open-label, pivotal trial studying the safety and pharmacokinetics of Lumitrace and the use of the TGFR in subjects with normal and impaired renal function, and with different skin color types comparing the Average Session GFR to plasma derived indexed GFR (nGFR) (measured GFR).

The primary endpoint of the pivotal clinical study was the performance measure of P30 for Average Session GFR with respect to nGFR, with a lower limit of the 95% confidence interval greater than 85%.

This P30 value is the number of measurements of Average Session GFR that differ by no more than 30% from the measurement of nGFR.

The clinical study endpoints were achieved and the data can be reviewed in the tables below.

The bridging study for the TGFR Reusable Sensor was a multi-center, open-label, adaptive bridging study comparing the transdermal glomerular filtration rate (tGFR) of subjects with normal and impaired renal function, and with different skin color types, to plasma-derived indexed GFR (nGFR) with Lumitrace® (relmapirazin) injection. After 75 evaluable subjects in the validation cohort was complete, an interim analysis was conducted to compare results against the primary endpoint specifications. To control alpha error in the interim analysis, alpha was lowered from 5% to 3% in the endpoint analysis. The study was designed to be terminated if the interim analysis met the endpoint.

The primary endpoint of the bridging study was the performance measure of P30 for transdermal-derived Average Session GFR with respect to the plasma-derived indexed GFR, with a lower limit of the 97% CI greater than 85%.

The bridging study endpoints were achieved and the data can be reviewed in the tables below.

Average Session GFR with the single use sensor - results comparison with measured GFR results (nGFR in the pivotal trial):

94% of the Average Session GFR values obtained using this device were within 30% of the measured GFR values (with a confidence interval of 89.4%-96.9%).
This was the outcome of the pivotal trial.

Single use Sensor – Pivotal Study – 5% Alpha

P30 Value	Upper 95% CI	Lower 95% CI
94.0%	96.9%	89.4%

Average Session GFR with the Reusable Sensor - results comparison with measured GFR results (nGFR in the bridging study):

96% of the Average Session GFR values obtained using this device were within 30% of the measured GFR values (with a confidence interval of 87.9% - 99.3%).
This was the outcome of the bridging study.

Reusable Sensor – Bridging Study – 3% Alpha

P30 Value	Upper 97% CI	Lower 97% CI
96.0%	99.3%	87.9%

Average Session GFR with single use Sensor - results comparison with estimated GFR (eGFR) results (using the creatinine-based 2009 CKD-EPI equation):

TGFR with Single use Sensor	Average Session GFR	eGFR*
P30	94.0%	92.9%
95% Confidence Interval	89.4-96.9%	88.2-96.1%

Average Session GFR with Reusable Sensor - results comparison with estimated GFR (eGFR) results (using the creatinine-based 2009 CKD-EPI equation):

TGFR with Reusable Sensor	Average Session GFR	eGFR*
P30	96.0%	90.7%
97% Confidence Interval	87.9-99.3%	80.7-96.5%

*The eGFR results above were obtained via post hoc analysis (which was not the predetermined outcome measure from the studies).

In the pivotal trial with the single use TGFR Sensor, 94.0% of the Average Session GFR values obtained using this device were within 30% of the measured GFR values and 92.9% of the eGFR values (creatinine based 2009 CKD- EPI equation) were within 30% of the measured GFR values. In the bridging study with the TGFR Reusable Sensor trial, 96.0% of the tGFR values obtained using this device were within 30% of the measured GFR values and 90.7% of the eGFR values (creatinine based 2009 CKD- EPI equation) were within 30% of the measured GFR values. The confidence intervals overlap (see table above).

Additionally, data was evaluated in subgroup populations seen in the tables below.

Subgroup Population Results

Patient Population	P30 Value **TGFR Sensor**	95% Confidence Intervals **TGFR Sensor**	P30 Value **TGFR Reusable Sensor**	97% Confidence Intervals **TGFR Reusable Sensor**
Stratum 1 (eGFR ≥70 mL/min/1.73m^2)	95.6% N=90	89.0% - 98.8%	95.0% N=40	81.7% - 99.5%
Stratum 2 (eGFR < 70 mL/min/1.73m^2)	92.4% N=92	84.9% - 96.9%	97.1% N=35	83.6% - 100.0%

Patient Population	P30 Value **TGFR Sensor**	95% Confidence Intervals **TGFR Sensor**	P30 **TGFR Reusable Sensor**	97% Confidence Intervals **TGFR Reusable Sensor**
FSS Type I-II	96.1% N=77	89.0% - 99.2%	100% N=25	84.5% - 100.0%
FSS Type III-IV	92.8% N=69	83.9% - 97.6%	92.3% N=26	72.9% - 99.3%
FSS Type V-VI	91.7% N=36	77.5% - 98.3%	95.8% N=24	76.9% - 99.9%

The following may affect the effectiveness/accuracy of this device:

- Subjects were enrolled across a range of skin tones, but individual skin tones were not powered to provide statistical significance (see data above).
- IV fluid bolus administration
- Patient movement during the 8-24 hours that the device takes to produce GFR results.

16 HOW SUPPLIED/STORAGE AND HANDLING

- Lumitrace is provided as a sterile, pyrogen-free, clear orangish solution in an amber glass vial.
- Lumitrace injection may be sensitive to light and therefore should be protected from exposure.
- Store the vials in original cartons at refrigerated conditions 2°-8°C (36°- 46°F); excursions permitted to 15°-30°C (59°-86°F) for 72 hours.
- Do not freeze.

Reference UDI below.

17 PATIENT COUNSELING INFORMATION

Patients receiving injectable diagnostic tracer agents should be instructed to:

- Read Patient FACT Sheet which will be provided to them by their health care provider.
- Discuss advantages and disadvantages of this method of GFR determination and compare with other available methods.
- Inform your physician if you are pregnant (see 9.1).
- Inform your physician about any other medications you are currently taking, including non-prescription drugs, before you are administered this tracer agent.
- Urine may be discolored following dosing until the tracer agent is cleared.

Manufactured for:
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Patents: www.medibeacon.com/patents

Revised: May 15, 2026

Unique Device Identifier Numbers (UDI)

The UDI numbers for the Lumitrace, injection for intravenous use are:

Individual vial 00860008387165YYYYMMDD.

The UDI number for the 10-vial carton of Lumitrace, injection for intravenous use is a 10-vial carton 20860008387169YYYYMMDD

The UDI number for the case (50 vials) of Lumitrace, injection for intravenous use is Case of five 10-vial cartons 30860008387166YYYYMMDD

YYYYMMDD is the year, month, and day of manufacturer