FACT SHEET FOR HEALTHCARE PROVIDERS

MediBeacon®
Transdermal GFR System

January 14, 2025

Point of Care GFR Assessment

This Fact Sheet informs you of the probable risks and benefits of the use of the MediBeacon® Transdermal GFR System (TGFR).

Indications 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 m^2, GFR >120 ml/min/1.73m^2, 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 Sensor and exogenous tracer agent, Lumitrace® injection, are single use and are only used with the MediBeacon® TGFR.

The MediBeacon® TGFR Sensor is a single use device intended to attach to the patient's skin and 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.

Contraindications: There are no known contraindications.

All patients will receive the Fact Sheet for Patients: MediBeacon® Transdermal GFR System (TGFR).

What is the MediBeacon® Transdermal GFR System (TGFR)?

The MediBeacon® Transdermal GFR System (TGFR) provides an assessment of glomerular filtration rate (GFR) at the point of care. This system employs an intravenously administered fluorescent tracer agent which has been engineered to be excreted exclusively by the kidneys. Noninvasive transdermal fluorescence detection of the excretion rate of the agent is converted into a GFR reading by this system.

The Instructions for Use can be found at IFU.MediBeacon.com.

What fluorescent tracer agent is used as part of the TGFR?

The MediBeacon TGFR includes Lumitrace (relmapirazin), an exogenous GFR tracer agent administered as an IV bolus injection.

Full prescribing information can be found at IFU.MediBeacon.com.

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- **Not for use in patients with dynamic or rapidly changing kidney function.**
- **Lumitrace® injection has light absorbance at 266 nm and 435 nm, and broad fluorescent emission at ~560 nm when excited at ~440 nm. Any drug activated at these wavelengths should not be used in conjunction with Lumitrace.**
- **Lumitrace injection may interfere with some in vitro clinical laboratory tests. The presence of Lumitrace decreased B-Type Natriuretic Peptide (BNP) results by around 20% in limited in vitro laboratory 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).**

Report Adverse events, including problems with device performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/) or by calling **1-800-FDA-1088**

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TGFR Key Components:

- Lumitrace® (relmapirazin) injection is the novel and proprietary fluorescent tracer agent, intravenously administered to a patient and then subsequently excreted from the body by the kidneys.

- MediBeacon® TGFR Sensor is a single use, sensor containing the light source and photo detector for the noninvasive detection of the transdermal fluorescence from Lumitrace injection and is attached to one of several positions on the body using a biocompatible adhesive. This transdermal sensor has a built-in cable that connects to a display monitor.

- MediBeacon® TGFR Monitor is the display monitor and provides power to the TGFR sensor, provides the user interface, digitizes the data acquired from the TGFR Sensor, contains the algorithms to run the TGFR Sensor and convert the output to GFR, and displays the GFR to the clinician and/or caregiver.

Key Characteristics

- Point of Care
- May take 8-24 hours to yield GFR results depending on the patient's renal function
- No blood draws
- IV line insertion required
- No urine collection
- Nonradioactive, non-iodinated fluorescent tracer agent
- Limited patient movement allowed for 8-24 hours while the GFR is being assessed.

Accuracy

A. Average Session GFR 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.

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

B. Average Session GFR results comparison with estimated GFR (eGFR) results (using the creatinine-based 2009 CKD-EPI equation)

	Average Session GFR	eGFR*
P30	94.0%	92.9%
95% Confidence Interval	89.4-96.9%	88.2-96.1%

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

In the pivotal trial, 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. The confidence intervals overlap (see table above).

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Clinical Study Performance Results

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 value computed from transdermal GFR (tGFR) values to plasma derived indexed GFR (nGFR), measured GFR.

The primary endpoint of the pivotal clinical study was the performance measure of P30 for the Average Session GFR with respect to nGFR, with a lower limit of the 95% confidence interval greater than 85%. This means that 94% of Average Session GFR values were within 30% of the measured GFR (which was the reference standard), with a confidence interval of 89.4-96.9%.

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

The clinical study yielded a P30 value of 94.0%, with a lower 95% confidence interval of 89.4% (and an upper 95% confidence interval of 96.9%). Thus, the primary endpoint was achieved. This means that 94% of the Average Session GFR values (with a confidence interval of 89.4 -96.9%) were within 30% of the measured GFR values (nGFR).

Patients were grouped into Stratum 1 (eGFR ≥70 mL/min/1.73m^2) and Stratum 2 (eGFR < 70 mL/min/1.73m^2). For Stratum 1 the study yielded a P30 value of 95.6%, with a lower 95% confidence interval of 89.0% (and an upper 95% confidence interval of 98.8%). For Stratum 2 the study yielded a P30 value of 92.4%, with a lower 95% confidence interval of 84.9% (and an upper 95% confidence interval of 96.9%).

Clinical Study Performance Results (continued)

Fitzpatrick Skin Phototypes (FSP) groups, FSP Type I-II (N=77), FSP III-IV (N=69) and FSP Type V-VI (N=36). For FSP Type I-II, the study yielded a P30 value of 96.1%, with a lower 95% confidence interval of 89.0% (and an upper 95% confidence interval of 99.2%). For FSP Type III-IV the study yielded a P30 value of 92.8%, with a lower 95% confidence interval of 83.9% (and an upper 95% confidence interval of 97.6%). For FSP Type V-IV the study yielded a P30 value of 91.7%, with a lower 95% confidence interval of 77.5% (and an upper 95% confidence interval of 98.3%).

In post hoc analysis, which was not the predetermined outcome measure from the study, the screening eGFR was compared to the plasma GFR of Lumitrace resulting in a P30 of 92.9% (CI 88.1%-96.1%). The eGFR was calculated using the creatinine-based 2009 CKD-EPI equation.

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.

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Product Safety Information

In clinical trials, there were no serious adverse effects or deaths. For patients receiving a 7 ml dose of Lumitrace, the most common adverse effects included:

- Injection site extravasation (9/412, 2%)
- Headache (5/412, 1%)
- Ecchymosis (3/412, 1%)

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.

There are no data on the presence of relmapirazin in human milk, the effects on the breastfed infant or the effects on milk production.

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.

What are the approved available alternatives?
The most common clinical practice for GFR estimation is to use a clinical laboratory test for creatinine and/or cystatin C levels and an estimation equation.

Precautions:

- Not MRI compatible
- Bolus fluid infusions may impact the GFR readings temporarily while the vasculature-tissue equilibrium is reestablished
- High energy electromagnetic and radio frequencies (e.g., cauterizing or electrosurgical equipment) may interfere with system performance

Where can I go for updates?

Clinical practice guidelines and CDC Kidney Disease Surveillance System can be accessed electronically at these websites:

- **KDIGO Guidelines: Guidelines – KDIGO**
- **CDC Kidney Disease Surveillance System: Kidney Disease Surveillance System (cdc.gov)**

Additional information on the MediBeacon Transdermal GFR System is available on the MediBeacon website

MediBeacon Inc.:
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