FACT SHEET FOR PATIENTS

MediBeacon®
Transdermal GFR System

January 14, 2025

Point of Care GFR Assessment

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

- The MediBeacon TGFR detects the change in levels of an intravenously administered fluorescent tracer agent (Lumitrace) over time using a sensor placed on your skin to assess your Glomerular Filtration Rate (GFR).
- A TGFR session helps your doctor to assess your kidney function. Your doctor has reviewed your medical records and has determined that you would benefit from a kidney function assessment using Lumitrace tracer agent as part of a TGFR session.
- Use of this device is by prescription only.

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.

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What is Lumitrace?

- Lumitrace is a prescription product called a fluorescent tracer agent. Lumitrace, like other fluorescence agents, is injected into a vein and Lumitrace is used as part of the MediBeacon Transdermal GFR System (TGFR).

What is the most important safety information I should know about the TGFR?

- Lumitrace is excreted by the kidneys in the urine and can stay in your body for up to 72 hours if you have impaired kidney function.
- It is not known if Lumitrace can interfere with other tests your healthcare provider may prescribe. If you undergo any other tests within 72 hours after your injection, **you should tell your healthcare provider that Lumitrace may interfere with the results.**
- It is not known how Lumitrace may affect you, but so far, clinical studies have not found harmful effects in patients receiving Lumitrace.
- Rarely, patients can feel a headache or have bruising at the site of the injection, but these symptoms have not been directly linked to Lumitrace.
- Urine may be discolored (orange) for 1 to 3 days after receiving Lumitrace depending on your kidney function.
- There is no information available on the presence of relmapirazin in human milk, the effects on the breastfed infant or the effects on milk production.

Do not receive Lumitrace if you have had a severe allergic reaction to Lumitrace or to any of the ingredients in Lumitrace. See the end of this leaflet for a complete list of ingredients in Lumitrace.

Are there any alternatives available?

Yes, there are alternative methods that utilize blood or urine samples. Discuss the benefits and risks of each method with your doctor.

How do I prepare for a TGFR Session?

- Before a TGFR session, do not apply any lotions or creams to your upper chest area and do not use spray tanning as these can prevent the sensor from attaching and reading correctly.
- Wear comfortable light-fitting clothing.
- You can follow your normal diet and take your medications at their normal time.

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What can I expect in a TGFR Session?

- On the day of your TGFR session, a small sensor will be taped to your upper chest area. If you have hair in that area, it will be clipped prior to the sensor being attached with tape.
- You will be asked to stay still for about 20 minutes to make sure the sensor is attached and reading properly.
- After that time, you will have an injection into an intravenous (IV) line with Lumitrace.
- While Lumitrace is in your system you will remain in the clinic or hospital for up to 24 hours until the session is done.
- It is important to leave the sensor in its original position and not remove it until your session is complete.
- Minimal movement is allowed during the TGFR session. However, you may eat, drink, go to the bathroom, sleep, watch tv, read, or other sedentary activities while the session is in process. **Do not lie on your side or stomach while the sensor is attached.**
- If you remove the sensor or leave the clinic prior to finishing a session, your doctor may not get the information on your kidney function, and you may be asked to repeat the test.
- Once the session is complete, your results will be recorded, and the sensor removed by the nurse.

Before having a TGFR session, tell your healthcare provider about all your medical conditions, including if you:

- have had any allergic reactions to other medications
- are taking any other medications including non-prescription drug products
- are nursing, pregnant or plan to become pregnant. It is not known if Lumitrace can harm your baby. Talk to your healthcare provider about the possible risks to a baby if Lumitrace is received during pregnancy or while breast feeding.

What are the possible side effects of the TGFR?

- **See "What is the most important information I should know about the TGFR?"**

The most common side effects of Lumitrace injection include headache, tracer leakage and injection site bruising.
These are not all the possible side effects of Lumitrace.
There may be irritation at the sensor site if you are sensitive to medical tape.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088, or at https://www.accessdata.fda.gov/scripts/medwatch/.

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

General information about the safe and effective use of the TGFR
You can ask your healthcare provider for information about the TGFR that is written for health professionals.

What are the ingredients in Lumitrace?

Active ingredient: relmapirazin
Inactive ingredients: Sodium Chloride, Sodium Dihydrogen Phosphate Monohydrate, and Water for injection. Sodium hydroxide and/or hydrochloric acid may have been used to adjust the pH.

Manufactured for MediBeacon Inc.
Lumitrace Injection is manufactured in USA or China
TGFR Monitor and TGFR Sensor are manufactured in USA

For more information, go to www.MediBeacon.com or call 1-314-269-5808.