



## **BRIEF SUMMARY INSTRUCTIONS**

This leaflet does not include all the information needed to use CirrhoCare safely and effectively. Please see directions for use within the CirrhoCare app for important safety information or reach out to CyberLiver for a complete user manual.

### **Indications for use:**

CirrhoCare will be applied for out-of-hospital specialist Hepatology follow-up and intervention of all adult cirrhosis patients, at risk of acute cirrhosis decompensation. Its principal use is foreseen in patients being discharged from the hospital following recovery from acute cirrhosis decompensation for the assisted diagnosis of new complications of cirrhosis and their early intervention. As such, potentially preventable causes of cirrhosis decompensation when diagnosed, such as dehydration or hepatic encephalopathy, would be managed by a prescription digital therapeutic intervention by CirrhoCare. In patients who remain stable on CirrhoCare Management follow-up for up to 6 months, a more standard medium-term outpatient clinical follow-up pathway could be resumed. For those who remain unstable or with signs of frequent new complications, CirrhoCare PDT management would be continued beyond 6 months.

### **Important Safety Information:**

If you have a health emergency, immediately go to the nearest A&E or urgent care.

Read and understand the manual and its safety instructions for each element of the health kit, if available, before usage.

Follow the instructions that are displayed on the app. Follow each step in the sequence. During usage, please put each element of the health kit on a safe, flat surface before use. Make sure the devices are charged as appropriate. Do not mishandle the health kit. Do not expose the kit to heat or moisture.

### **Patient eligibility:**

CirrhoCare is intended only for patients with smartphone literacy.

You should have access to an Android/iOS smartphone and be familiar with the use of smartphone applications (apps). You should be able to upload data periodically, i.e., have internet/wireless connection access.

CirrhoCare is intended for patients who are enrolled under the prescription therapy program.

### **What is CirrhoCare?**

CirrhoCare® is one of a new class of therapeutics called Prescription Digital Therapeutics (PDTs). It is designed specifically for the diagnosis of further cirrhosis complications and/or organ dysfunction for patients at home.

The CirrhoCare health kit comes with the CirrhoCare App installed on the smartphone, an ECG monitor, a Blood pressure monitor and a weighing scale.

## How to start using CirrhoCare?

- The CirrhoCare App will be pre-installed on your smartphone and ready to use.
- The medical personnel will instruct you during your induction on the app usage. Your device will be already connected and “synced” to the app and ready to use.
- Your app will be personalised based on your prescription. You will have any or all of these elements on your app according to your prescription.
  - ECG
  - Blood pressure
  - Weight
  - Feeling
  - CL-ART
  - Food & fluid
  - Temperature
  - Medications
- There will be a detailed step by step guide on your app for taking all measurements. Please follow all those instructions to get the correct measurement.
- The app will automatically trigger reminders at the start of your day with a voice note and point to the ECG measurement guide screen, which will be your first measurement, which will be done with your ECG watch and smartphone.
- The second measurement you will be asked to take will be your blood pressure. You will need your blood pressure monitor and your smartphone.
- The third measurement you will be asked to take will be the weight. You will need your weigh scale and your smartphone.
- The app will collect your mood, activities, diet, and general attitude toward your conditions. Please try to be as specific as possible because every little thing counts.
- CL-ART is a test used to assess your brain function and thinking abilities.
- You will be asked to record your food and fluid intake.
- Occasionally, the app will ask you to take your temperature using a basic forehead thermometer strip if you feel poorly. You can measure your temperature if you are developing a cough or urinary symptoms or if your ECG and blood pressure measures alert the clinical team to a suspected new infection.
- Your app may remind you of your medications based on your prescription. When prompted, make sure you take your medication as required and record it on the app.
- The app also acts as a bi-directional communication channel, using which you can leave a message for your clinical team to follow up on if there is anything about which you are worried or wish to inform them and see what messages the clinical team has left for you.
- CirrhoCare primarily aims to monitor patients in near real-time and potentially prevent the occurrence of cirrhosis decompensation events.

For detailed instructions on how to use the app, please check the in-app instructions.