

PATIENT INFORMATION

Brief Summary Instructions

This patient information leaflet does not include all the information needed to use CirrhoCare® safely and effectively. Please use the CirrhoCare® learning guide and follow the instructions displayed on the App.

Intended Use

CirrhoCare® is intended for monitoring and managing decompensated cirrhosis with assisted diagnosis, recommendations, and therapeutic interventions

Indications for Use:

CirrhoCare® is intended for out-of-hospital specialist hepatology management follow-up of adult cirrhosis patients aged 18 and older. CirrhoCare® is intended to identify new preventable decompensation events [such as dehydration (acute kidney injury), new accumulation of ascites, infection or hepatic encephalopathy] for a healthcare provider to take immediate clinical action, allowing the opportunity for early outpatient-based interventions.

CirrhoCare® is intended for active remote management for up to 6 months. A more standard medium-term outpatient clinical follow-up pathway can be resumed in patients who remain stable on CirrhoCare® for up to 6 months. For those who remain unstable or with signs of frequent new complications, management can be continued beyond 6 months.

Important Safety Information:

Do not use CirrhoCare® to communicate any urgent or emergent information to your clinician. CirrhoCare® does not include any features that can send emergency alerts to your clinician.

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

Use the guide on the App before using each device in the CirrhoCare® healthkit.

Ensure devices are charged as necessary, and avoid mishandling the healthkit. Keep the healthkit away from heat and moisture to maintain optimal performance.

Patient eligibility:

Patients aged 22 or older.

CirrhoCare® is intended only for patients with smartphone literacy.

You should have access to an Android/iOS smartphone with an active internet connection and be familiar with smartphone applications (apps).

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

What is CirrhoCare®?

The CirrhoCare® device is a multi-modal monitoring and management system for application for out-of-hospital specialist hepatology follow-up of all adult decompensated cirrhosis patients at risk of new, acute cirrhosis decompensation.

The CirrhoCare® system is comprised of (a) commercially available sensors from 3rd party, including a SmartWatch and/or ECG monitor, blood pressure monitor, a bio-impedance weighing scale, and the (b) CirrhoCare® app, which receives inputs from each component, assess cognitive ability using CyberLiver® services and record medication adherence, patient-reported symptoms and outcomes in the app and (c) a proprietary built-in algorithm which combines this data with patient recordings on feelings of wellbeing, food, and fluid intake and send to a (d) CyberLiver® clinician dashboard.

How to start using CirrhoCare®?

After the prescription of CirrhoCare® by the clinical team, CirrhoCare® healthkit that has a pre-installed CirrhoCare app and Bluetooth connected wearables will be assigned and given to you for use

Upon admission to CirrhoCare®, the medical staff will provide instructions on how to use the app. Alternatively, you can set up the app on your own by following the step-by-step instructions provided in the CirrhoCare® app. Your healthkit devices will be synced to the app and readily available for use.

Your CirrhoCare® app and healthkit will be personalised based on your prescription. Your App can use any or all of these elements based on your prescription.

- Smart watch for physical activity, sleep and ECG
- Blood pressure
- Weight
- Cognitive ability test
- Well-being
- Treatment plan
- Body temperature
- Food, fluid and nutrition

Your App will have a detailed step-by-step guide for taking all measurements and recording patient-reported outcomes. Please follow all those instructions to get the correct measurement; you will need your smartphone for all the steps.

Occasionally, the App or your provider will ask you to take your temperature using a forehead/ear thermometer.

Your App may remind you of your medications based on your prescription. When prompted, take your medication as required and record it on the App.

The App also acts as a two-way communication channel. 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 help clinical users prevent new cirrhosis decompensation events.

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

What Operating Systems Does CirrhoCare® Support?

The CirrhoCare® app is supported on the following mobile operating systems:

- iOS
- Android

For a full list of compatible phones and specifications, please visit the link here <https://cirrhocare.com/compatibility>

General Information about the Safe and Effective Use of CirrhoCare:

You should only use CirrhoCare® if enrolled in a Cirrhosis treatment program. CirrhoCare® is meant to be used in conjunction with your standard treatment pathway. CirrhoCare® is not intended to reduce face-to-face time with your clinician.

Additional Support Available: For additional support with any aspect of the CirrhoCare®, contact us via email at help@cyberliver.com.

Rx Only