



Instructions for Use

florio® TRICARE

Version 1.0.x, Date 22.05.2026

Revision A



Intended purpose	florio TRICARE is a digital support solution for people living with severe hypertriglyceridaemia (sHTG) including familial chylomicronaemia syndrome (FCS), a severe blood fat disorder, to alleviate the daily burden of the disease. florio TRICARE enables lay users to record and organise their health and treatment information, disease-related symptoms, medication, and diagnostic results, to support management of their condition. florio TRICARE allows lay users and professional users to review contextualised treatment information, individual treatment outcomes, personalised trends and analyses. The application does not provide specific treatment recommendations to the user or their HCP (healthcare professional).
Indications	Severe hypertriglyceridaemia (sHTG) including familial chylomicronaemia syndrome (FCS).
Contraindication	florio TRICARE is not intended to be used by users with a disease other than severe hypertriglyceridaemia (sHTG) including familial chylomicronaemia syndrome (FCS).
Patient selection criteria	App user: Patients diagnosed with severe hypertriglyceridaemia or familial chylomicronaemia syndrome (≥ 18 years old).
Side effects	No side effects were identified for florio TRICARE.
Warnings	Warnings have not been identified to date.
Precautions	Entering wrong information into the app can lead to the display of erroneous data and notifications in the app. This can also be caused by connectivity issues, application errors, or cyber-attacks. If you feel that the information displayed in the app is not in line with your prescribed treatment, please, stick to the prescribed treatment and consult your doctor. Please make sure that you have always installed the latest version of florio TRICARE.
	Please, only use florio TRICARE in accordance with its intended use.
	Please make sure you keep your login credentials safe. Sharing your login information with other people may potentially compromise your personal data.
Lifetime	The expected device lifetime is 2 years.

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1. About florio TRICARE

The florio TRICARE app combines both, condition monitoring and tracking of dietary habits within one digital solution. Analyses and visualisations of your logged data are designed to support you with the self-management of the disease.

The florio TRICARE app requires an internet connection.

2. Get started

Download the florio TRICARE app from the Apple App Store or Google Play Store. Ensure not to use any other source for downloading.

Set-up your account by entering your email address and choosing a password. For security the app uses two factor authentication. Follow the instructions on the screen and accept the terms and conditions of the app.

3. Home screen and menu

The home screen provides you the following information:

- Search bar for nutrition tracking
- Your medication-section to take control of your medication
- Explore recipes and mark what you liked
- Tips and tricks for your diet

Use the menu on the bottom to access the sections  home,  trends,  recipes and  settings. Use the

 plus button to log events.

4. Treatment plan

4.1.Set up

After you have created your account, you will be asked to complete your treatment plan. Follow the steps on the screen to finish the set up.

To access the section and add a treatment plan, select  settings in the menu and tap on “Treatment plan”.

4.2.Medication reminders

During the creation of your treatment plan, you can set up medication reminders. If you would like to enable them later, follow the instructions in the next section on how to edit a treatment plan. Once enabled, you will get reminders at the time of your choice.

To receive medication reminders, you must give florio TRICARE permission through your phone settings.

Please always take your medication as prescribed by your doctor.

4.3.Edit, end or delete a treatment plan

Select  settings in the menu and tap on “Treatment plan”. Select the treatment plan you would like to edit, end or delete.

- **Edit:** Edit a treatment plan if you did a mistake or if you want to switch on/off reminders. Tap

on “Edit” and change the relevant fields. If you changed the dose or frequency, to track the changes florio TRICARE will end your current treatment plan and save a new one with your updates.

- End: End a treatment plan if you started a new medication, dose or interval. Tap on “End”, select the end date and confirm.
- Delete: It is recommended not to delete past treatment plans. They will be part of your treatment plan history and will be valuable information over time. We recommend deleting treatment plans only if you did a mistake that cannot be corrected. If you really want to delete a treatment plan, please note that only treatment plans with a start date in the future or already ended treatment plans can be deleted. Tap on “Delete this treatment plan” and confirm.

5. Recipes

Select  recipes in the menu. You can explore here a variety of different recipes for breakfast, lunch, dinner and snacks. The section offers also daily plans for different energy levels based on your planned calorie intake.

6. Record events

Tap on the  plus button on the home screen and follow the instructions on the screen.

6.1.Dietary logging

Log your meals via the search bar on top of your home screen or the plus button on the bottom to keep track of your fat and calorie intake. You can type in food, ingredients or dish names, use the camera to scan barcodes or your entire meal or select the voice assistant to log your meals. Follow the instructions on the screen to finish logging. You can only use one logging method at a time. Complete your current log before using a different method.

Image recognition via your camera is using AI (artificial intelligence). Review items and adjust portion sizes as needed, as information may be inaccurate.

6.2.Biomarkers

You can log triglycerides in florio TRICARE. Please always log the units as stated in your lab report. The app also allows you to log your weight and height.

6.3.Symptoms

Log your symptoms like fatigue, pain, nausea and vomiting. Follow the instructions on the screen to finish logging.

6.4. Medication

Record your scheduled medication in florio TRICARE from your medication reminder, by tapping on the  plus button in the menu, or the plus button next to your scheduled medication on your home screen or by selecting the corresponding scheduled medication in your timeline. Follow the instructions on the screen to finish logging.

You can also log one-time medication by tapping on the plus button in the menu.

6.5. Edit or delete entries

You can either edit or delete entries.

Select  settings and go to  timeline. Select the log you would like to edit or delete and follow the instructions on the screen.

7. Visualise data

7.1. Timeline

Access the  timeline via  settings. The timeline provides you with a review of your logs, future events and your scheduled and taken medications in chronological order. The filter helps you to easily see selected logs.

7.2.Trends

The  trends section visualises your logged biomarkers and nutritional values, displays your BMI and trends of your recorded symptoms, and shows your medication adherence. Adherence calculation is based on most recent 30 days and is only available for disease-specific medication.

7.3.Health report

Your health report is a visual summary of your recorded data of the last six months.

Select  trends in the menu and tap on “Generate report”. Enter a nickname for the report – this name is not stored by florio TRICARE. Your health report will be generated as PDF. You can print or share it via communication apps installed on your phone (e.g. email).

8. Symbol explanation

Symbol	Explanation
	Indicates the item is a medical device
	The CE mark indicates conformity to the Medical Device Regulation (EU) 2017/745 with the notified body identification number
	Indicates the medical device manufacturer as defined in Medical Device Regulation (EU) 2017/745
	Indicates the date when the medical device was manufactured
	Indicates that relevant information for use of the product is available in electronic form rather than, or in addition to, printed paper form
	Indicates the Unique Device Identifier
	Indicates a medical device that may be used multiple times on a single patient
	Symbol to indicate that the system needs to be checked or updated
	Identifies that the original medical device information has undergone a translation which supplements or replaces the original information
	Navigates to the home screen
	Navigates to the trends screen
	Plus button on the bottom of the home screen: Navigates to new logs creation Plus button anywhere else in the app: Adds item
	Navigates to the settings screen
	Navigates to the timeline screen
	Navigates to the recipes screen
	Filters displayed items
	Edits item

Symbols	Explanation
	Deletes item
	Closes item
	Display additional information
	Indicates a decrease
	Indicates stable trend
	Indicates an increase
	Navigates to the meal logging screen based on camera input
	Navigates to the meal logging screen based on microphone input. Starts audio recording
	Pauses audio recording
	Submits text
	Adds item to favourites
	Removes item from favourites

9. Data protection

9.1.Data security

Take reasonable measures to protect your florio TRICARE app from unauthorised access,



e.g. perform software updates timely and regularly, set up password protection or biometric authentication of your phone and use device encryption.

You can activate security features for the florio TRICARE app in your mobile phone settings.

9.2.Data protection

Information about data protection is available in the Data Privacy Policy and Terms of Use for florio TRICARE, available at <https://dashboard.tricare.healthcare/v1/patient/legal-docs>

9.3.Account deletion

If you would like to delete your account, tap on  settings and tap on “Profile settings”. Tap on “Delete account” and follow the instructions on the screen to finish the account deletion.

With account deletion you will immediately lose access to your account.

You can delete the app from your device at any time.

10. Information for emergencies

10.1. Adverse events and complaints related to medication

florio TRICARE is not a tool for reporting suspected side effects (also known as adverse events) of your medication and does not store or submit records of it. Please consult your doctor with any questions or concerns you may have regarding your health condition. Relevant contact details for the manufacturer of your medication can be found on the manufacturer’s website. If there is any defect of content or function of florio TRICARE, please contact

help@florio.com without delay.

10.2. Incidents and complaints related to florio TRICARE

In case of medical emergency, please contact your doctor or dial the emergency number. If there is any defect as to the content or function of florio TRICARE or suspected security events the manufacturer should be contacted without delay at help@florio.com. For serious incidents, please contact the manufacturer via help@florio.com as well as your local competent authority.

11. Product disclaimer

The app is not intended to be used in place of advice from your physician or other healthcare professionals. Should you have any health-related issues contact your physician or other healthcare professional promptly. Should you have any questions on florio TRICARE please contact us at help@florio.com.

This device is intended solely for the purpose described in the Intended Purpose section of these instructions for use.

The application does not provide specific treatment recommendations to the user or their HCP.

The intended users are lay users (florio TRICARE App) with severe hypertriglyceridaemia (sHTG), including familial chylomicronaemia syndrome (FCS).

florio TRICARE is not intended to be used by users with a disease other than severe hypertriglyceridaemia.

12. Minimum IT requirements

The florio TRICARE app works on smartphones operating iOS and Android operating systems.

Minimum smartphone requirements:

- iPhone: supports latest major iOS version and at least one below
- Android: version 9.0 or newer versions
- The app is built for the average smartphone screen size that is typically between 6.1 and 6.8 inches. As minimum a screen size of 5.6 inches is required. The app requires a minimum smartphone screen resolution of 1792x828 pixels.
- Landscape mode is not supported.
- The use of foldable phones may not be supported if the screen in the folded/unfolded state is larger or smaller than a regular smartphone.

For requests, enquiries and technical questions or if you would prefer a printed version of the instructions for use, please send an email to help@florio.com.



Florio GmbH
Wilhelm-Wagenfeld-Str. 22
80807 München
Germany
www.florio.com



iOS app:
(01) 04260748180211 (8012) V1.0.0
Android app :
(01) 04260748180228 (8012) V1.0.0

Please, note that in case of software updates (bug fixes), the last digit of the UDI-PI (V1.1.x) may be different on the corresponding application "About" screen compared to this overview.