




## Instructions for Use

**florio® ITP app**

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Intended purpose	<p>florio ITP is a software intended to monitor treatment of immune thrombocytopenia (ITP), a rare haematologic disorder, and its outcomes.</p> <p>Lay users can record ITP-related events and view personalised data trends and analyses that help them manage their condition.</p> <p>These personalised data trends and analyses can be used to support treatment decision-making by HCPs.</p>
Indication	Immune thrombocytopenia (ITP)
Patient selection criteria	All patients diagnosed with immune thrombocytopenia, who have reached the age of majority within their respective country.
Type and duration of use	florio ITP is intended to be used regularly by users within their typical social environment. florio ITP can be used for a long period of time.
Lifetime	<p>The expected lifetime of florio ITP is 1 year.</p> 
Contraindications (when the product is not intended to be used)	florio ITP is not intended to be used by patients with a disease other than ITP. Additionally, the patient must not be classified as a minor which is defined as those who have not reached the age of majority in the jurisdiction in which they reside.
Side effects	No side effects were reported for florio ITP.
Warnings	Warnings have not been identified to date.
Precautions	<p>Entering wrong information into the app can lead to the display of erroneous data in the app which can lead to underdosing, overdosing or to reduced efficacy of your medication. This can also be caused by connectivity issues, application errors, unauthorized access 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. Sharing incorrect data with your HCP via the health report may lead to inaccurate data being taken into account when making potential treatment adjustments.</p> <p>Please make sure that you have always installed the latest version of florio ITP.</p> <p>Please make sure florio ITP is only used in accordance with its intended use. Using florio ITP for other indications may lead to incorrect treatment decisions.</p> <p>Please make sure you double check the email address if</p>

	you share your health report. Sharing the health report with the wrong recipient may potentially compromise your personal data.
	Please make sure you keep your login credentials save. Sharing your login information with other people may potentially compromise your personal data.

# Content

1.	About florio ITP .....	6
2.	Get started .....	6
3.	Home screen .....	7
4.	Menu .....	7
5.	Treatment plan .....	7
5.1.	Medication and dietary restriction reminders .....	8
5.2.	End or delete a treatment plan .....	8
6.	Appointments and surveys .....	9
6.1.	Create an appointment .....	9
6.2.	Delete an appointment .....	9
6.3.	Pre-appointment survey .....	9
7.	Record events .....	10
7.1.	Medication .....	10
7.2.	Platelet counts .....	11
7.3.	Personal logs (e. g., fatigue or bleed) .....	11
8.	Delete logs .....	11
9.	Visualise data .....	11
9.1.	Trends .....	11
9.2.	Activity data .....	12
9.3.	Health report .....	13
10.	Symbol explanation .....	14
11.	Data protection .....	15
11.1.	Protect your data .....	15
11.2.	Data protection in the app .....	15
11.3.	Data Governance Board .....	15
12.	Account deletion .....	15
13.	Information for emergencies .....	16
13.1.	Adverse events and complaints related to ITP medication .....	16

13.1.	Incidents and complaints related to florio ITP...	16
14.	Minimum IT requirements.....	17

## **1. About florio ITP**

florio ITP enables intuitive, simple and fast documentation and monitoring of ITP-related data. The visualisation of the entered data in the app and the display of trends can help with the self-management of the disease.

People with ITP can summarise data from florio ITP in a clear report and easily share it with their healthcare team using the florio ITP app. The information from the report can help the healthcare team to better understand the health situation and monitor therapy success.

The florio ITP app requires an internet connection.

## **2. Get started**

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


Follow the instructions on the screens and confirm the terms and conditions of the app. Set-up your account by entering your email address, a nick name, your country and age and choosing a password. florio ITP does not need your actual name.

### 3. Home screen

The home screen displays your last entered platelet count, and a summary of your personal logs added to florio ITP from the last 30 days.

Additionally, medication reminders scheduled for that day are displayed. Tap on the “+” button to log events. On the bottom of your Home screen there is a timeline with your logged events. Extend the box by pulling it up.

### 4. Menu

You can access the main menu by tapping on the menu symbol  on the top left corner of the home screen. The menu provides you with quick access to “Home”, “Trends”, “Treatment plan”, “Appointments”, “Profile”, “Support”, and the “About” sections.

### 5. Treatment plan

You can enter the medication(s) and other treatments you are currently taking by tapping on “Treatment plan” in the main menu and select “Add treatment”. Select the type of treatment you wish to add and follow the instructions on the screens to finish the set-up.

florio ITP does not provide recommendations to the user to alter a previously prescribed treatment or therapy. 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.

## **5.1. Medication and dietary restriction reminders**

During the setup of your treatment plan you may set up medication reminders. Once enabled, you will get a reminder at the time, you usually take your medication.

Some ITP medications require dietary restrictions to be respected around the time that you take your dose. For those medications you can set dietary restriction reminders during the treatment plan set up.

To receive medication and dietary restriction reminders, you must give florio ITP permission through your phone settings to send you push notifications. Please always take your medication as prescribed by your doctor.

## **5.2. End or delete a treatment plan**

At the “Treatment plan” screen tap “...” next to the treatment you wish to end. From the options that appear, select “End treatment” and select end date. The ended treatment plan is then stored and displayed under “Past Treatments”.

If you have made a mistake while adding a treatment delete that treatment from your treatment plan. At the “Treatment plan” screen tap “...” next to the treatment you wish to delete. From the options that appear, select “Delete treatment”.



## **6. Appointments and surveys**

### **6.1.Create an appointment**

To add an upcoming appointment, navigate to the “Appointments” screen via the main menu:

- If you have never added an appointment before, there will be a prompt shown on the Home screen to create one. Tap on it and the appointments screen will open.
- Otherwise, open the main menu and tap on “Appointments”.

Now tap on the green “+” button. Select the appointment type from the available list and fill in the required fields.

### **6.2.Delete an appointment**

If you have erroneously entered an appointment, delete it from the appointment list. From the appointments screen tap “...” next to the appointment you wish to delete. From the options that appear, select “Delete”.

### **6.3.Pre-appointment survey**

If you have created a consultation appointment, you can complete a pre-appointment survey within 48 hours before the appointment. To complete the survey, you can tap on the pre-appointment survey prompt from

either:

- the „Home“ screen
- the “Appointments” screen.

You will be guided through a series of short questions to gather information about the impact of ITP on your daily life. For each question, simply select the response that describes best your situation.

Once the survey is complete, you can create a health report and optionally share the report with your doctor or healthcare team. If you wish to view your answers of the survey, you can do this via the health report prompts from either:

- the „Home“ screen
- the “Appointments” screen.

These prompts will appear until the day after the scheduled date of your consultation appointment.

## **7. Record events**

You will need an internet connection to log events like medications, platelet counts and personal logs.

### **7.1.Medication**

Record your taken medication by tapping on the “+” button on your Home screen. Follow the instructions on the screens to finish logging. Medication logs currently can`'t be deleted.

## **7.2. Platelet counts**

You can log platelet counts from the home screen:

- If you have never logged a platelet count before and are using florio ITP for the first time, tap the “Add platelet count” button.
- Otherwise, tap on the “+” button on your Home screen and select “Platelet Count”.

Follow the instructions on the screens to finish logging.

## **7.3. Personal logs (e. g., fatigue or bleed)**

Tap on the “+” button on your Home screen. Select what you wish to log and follow the instructions on the screens to finish logging.

## **8. Delete logs**

If you have made a mistake while entering data, delete the existing log. Navigate to the timeline of your logged events on the Home screen. Tap on an event to view more information about it and to get the possibility to delete it.

## **9. Visualise data**

### **9.1. Trends**

Navigate to the main menu and tap on “Trends”. This shows you a summary of your recorded data. At the top of the “Trends” screen you can select the time frame (30 days, 3 months, or 6 months).

In the 30-day time frame you can also view your

medication adherence. “Adherence” expresses how well you follow your treatment plan. For example, if you are directed by your doctor to take your medication daily for the last 30 days, and you logged your doses only 20 times in florio ITP, your adherence score will show 66% (20 out of 30).

In the 3- or 6-month time frames a timeline graph is shown. If you switch to landscape view you can tap on a month to see a detailed breakdown of the logs within that month.

## **9.2.Activity data**

If you have a wearable device, such as a smartwatch or fitness tracker, you can record activity data from such devices in florio ITP. For florio ITP to access your physical activity data, you must:

- 1) Install and set up Apple HealthKit (iOS phones) or Google Fit (Android phones) on your mobile phone
- 2) Set up your wearable device for data sharing with your mobile phone
- 3) Open florio ITP, select “Trends” via the main menu, scroll to the bottom and tap on the “connect activity” banner
- 4) You will be directed to a confirmation area to complete the data sharing with florio ITP

After completion, your activity data will be synced with florio ITP and shown within the activity section of the

“Trends” screen.

Data on physical activity is supplied to florio ITP by third party providers (Google Fit or Apple Health Kit). Florio GmbH does not have control over this data and cannot guarantee the accuracy of such data. The accuracy of this data depends on your input and is used and managed in your own responsibility.

### **9.3. Health report**

Your health report is a six-month summary of your recorded data including the results of your latest pre-appointment survey, if completed.








Navigate to the “Trends” screen and tap on “Generate report”. You can enter an optional name to appear on the report – this name is not stored by florio ITP. Now choose to either “View health report” or “Share health report”.

If you choose to view your report, you will be shown an in-App PDF.

If you choose to share your health report, you will see pop-up icons that show the possible communication applications (e.g. message, email, WhatsApp) that you can use to share a link to your report with a recipient of your choice like your doctor. There will be an auto-generated message which can be edited if required. However please do not remove, or alter the web-link and password as the recipient will need these to access

a copy of your health report. The recipient of your health report should open the report by clicking on the link they receive and entering the associated password. The web-link will only work when opened from a desktop browser, not a mobile phone or tablet.

## 10. Symbol explanation

Symbol	Explanation
	Medical device
	Indicates conformity with notified body identification number as defined in Medical Device Regulation (EU) 2017/745
	Indicates the medical device manufacturer as defined in Medical Device Regulation (EU) 2017/745
	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 updated
	Identifies that the original medical device information has undergone a translation which supplements or replaces the original information

## **11. Data protection**

### **11.1. Protect your data**



Take reasonable measures to protect your florio ITP 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 ITP app in your mobile phone settings.

### **11.2. Data protection in the app**

More information about data protection is available in the “Privacy Policy” and the “Terms of Use” for florio ITP, available at <https://florio-itp.com/legal>.

### **11.3. Data Governance Board**

Aiming to improve ITP care, your non-identifiable data may contribute to medical research. This information may be used for medical research purposes only and will be governed by an independent external Data Governance Board, consisting of international medical experts and patients’ associations representatives.

## **12. Account deletion**

If you like to delete your account, open “Profile” through the main menu. Tap on “Delete account” and follow the instructions on the screens. You can delete

the app from your device at any time.

## **13. Information for emergencies**

### **13.1. Adverse events and complaints related to ITP medication**

florio ITP is not a tool for reporting suspected side effects (also known as adverse events) of your medicine and does not store or submit adverse event reports. Please consult your healthcare professional with any questions or concerns you may have regarding your health condition. Relevant contact details for the manufacturer can be found on the manufacturers' website which should be on any medicine packaging.

### **13.1. Incidents and complaints related to florio ITP**

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 ITP or suspected security events, the manufacturer should be contacted without delay at [help@florio.com](mailto:help@florio.com).

For serious incidents, please contact the manufacturer via [help@florio.com](mailto:help@florio.com) as well as your local competent authority.



## **14. Minimum IT requirements**

florio ITP requires either of the following minimum operating systems:

- iPhone: supports latest major iOS version and at least one below, or
- Android: 9.0 and above.

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](mailto:help@florio.com).



Florio GmbH  
Wilhelm-Wagenfeld-Str. 22  
80807 München  
Germany  
[www.florio.com](http://www.florio.com)



iOS app:  
(01) 04260748180105 (8012) V5.1.1  
Android app:  
(01) 04260748180112 (8012) V5.1.1