

Levilog

Instructions for use

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1. About Levilog

1.1 Manufacturer

Navamedic AB
Göteborgsvägen 74
433 63 Sävedalen
Sweden

1.2 Intended purpose

Levilog is intended to support the treatment of Parkinson's disease by facilitating adherence to the prescribed medication. Levilog provides patients with reminders to help them take the right dose at the right time as well as to log and monitor their medication intake.

1.3 Who can use Levilog?

Levilog is intended for you if:

- You are using a medication supplied via an OraFID dose dispenser to treat your Parkinson's disease.
- You are 18 or older
- You are familiar with how to use smartphones and mobile apps.

1.4 Contraindications

The app should be used only to manage medication treatments supplied via an OraFID; it is not suitable for managing any other medication.

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1.5 How does Levilog work?

1.5.1 Timely medication reminders

Levilog will send notifications to alert you when it is time for your medication dose. When you tap on a notification, the app opens so you can register that you have taken the dose. Levilog also sends notifications when you start running out of tablets in your current OraFID dispenser, so you can make sure you have a new dispenser ready.

1.5.2 Log your doses

You can navigate to the "Your day" screen to log your scheduled doses or extra doses of your medication.

The more accurately you log your intake of your medication, the better the app will work for you. For example, you will receive timely reminders when your OraFID dispenser is running low and an accurate history as well as insights into how much medication you have been taking from day to day.

1.5.3 You need a valid prescription

To access Levilog, you will need a valid prescription for a medication supplied in an OraFID dispenser. To create an account, you will therefore need to confirm your prescription by scanning a number on your medication packaging or your dose dispenser, so make sure you have your medication nearby the first time you open the app.

2. Information on risks and benefits

2.1 Risks of using Levilog

There are no known serious risks associated with using Levilog. However, it is a support tool and should not be used as the only method to ensure proper medication management. The functionality of Levilog depends on correct user input, correct system settings, and a stable internet connection.

2.2 Benefits of using Levilog

Levilog will help you follow your prescribed dosage. By taking your medication at each prescribed time according to your doctor's instructions, you increase your chances of achieving stable relief from your symptoms.

2.3 Warnings and precautions

- **To receive medication reminders, you must allow the app to send notifications.** You will be asked to allow this when creating your account. If you say no, you can later go into the settings of your phone and enable notifications.
- **To continue receiving your medication reminders, you must open the app at least once a day when the phone is connected to the internet.** This way, you ensure that the app can always schedule new notifications.
- **To ensure you always receive reminders from Levilog, make sure your phone or tablet does not run out of battery.**
- When using the camera to add or update your dosing schedule, there may be certain limitations because the AI analysing the image may make errors. **It is therefore important that you always check the number of tablets and the timing of your doses when creating your schedule using the camera.** This way, you can ensure that your schedule is consistent with what your doctor has prescribed.

- **Change your schedule only according to your doctor's instructions.**
Levilog is designed so that you can customise your dosing schedule in the app according to the instructions your doctor has given. It's important to follow these instructions carefully.
- **Please be aware that the "Tablets left" function is affected by the start date and how you log your doses.** The app counts the total number of tablets in the dose dispenser and automatically deducts your scheduled doses – even if you don't actively log them. If you add extra doses, mark doses as "missed", or change the number of tablets in a dose, the app takes these changes into account and updates the calculation of remaining tablets.
- When you travel, your medication schedule automatically adapts to the time zone of your phone. For example, if you are taking a dose at 8:00 and travel to another time zone, you will receive a reminder to take the dose at 8:00 in the new time zone. **Before travelling between different time zones, it is important that you discuss with your doctor how to best manage your medication schedule.**

Report adverse or unwanted events, incidents, and accidents related to the use of Levilog to Navamedic AB and the Medical Products Agency.

2.4 Report serious incidents

Related to the use of Levilog to the manufacturer and the competent authority in the Member State where you are established (i.e. the Medical Products Agency (in Sweden), the Danish Tax Agency – Central Customs Division (in Denmark), Fimea – the Medications Agency (in Finland), and the Norwegian Medications Agency (in Norway)).

Please inform the manufacturer, Navamedic AB, by email: **info@navamedic.com**.

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3. Get started

3.1 Technical requirements

To use Levilog, you need access to a smartphone or tablet running iOS 18 or later or Android 15 or later. You also need a reliable internet connection.

3.2 Software updates and system requirements

To ensure the safe and efficient operation of the device, the following provisions apply to software updates and operating system compatibility:

3.2.1 Software and SECURITY UPDATES

- The application may receive regular software updates, including security fixes, performance improvements, and new features.
- Updates are delivered through the official app distribution platforms (Apple App Store or Google Play Store).
- The integrity and authenticity of all updates are automatically validated by the platform before installation.
- It is recommended that you enable automatic updates to ensure that the device is always running the latest validated software version.

3.2.2 System requirements

- Compatibility with newer operating systems is monitored and tested regularly; users may need to update the operating system on their device in order to maintain security and functionality.
- Using the application on unsupported or outdated operating systems may result in limited functionality or inability to use it.

3.3 Installation

3.3.1 To install Levilog on your iPhone or iPad:

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1. Open the App Store.
2. Type "Levilog" in the search field and find the app with the icon that looks like the attached logo.



3. Tap "Install"
4. Enter your Apple ID password.
5. Once the app is installed, tap the app icon to open Levilog.

3.3.2 To install Levilog on your Android:

1. Open Google Play Store.
2. Type "Levilog" in the search field and find the app with the icon that looks like the attached logo.



3. Tap "Install"
4. Once the app is installed, tap the app icon to open Levilog.

3.4 Registration

When you open the app, you will be taken to a welcome screen for the Levilog Starter Guide. Click "Start guide" to begin your registration.

3.4.1 Verify your prescription

After that, you will be asked to confirm that you have a valid prescription. You confirm this by entering the "VNR" number found on the packaging and the dose dispenser.

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There are two ways to do this:

1. By taking a photo with your camera of your dose dispenser or medication pack. Make sure to allow camera access when prompted. Then follow the instructions provided.
2. By entering the number manually. In this case, select the option "I don't want to use the camera". Then follow the instructions the app gives you.

3.4.2 Give the app permission to process your data.

You need to give your consent for Levilog to collect and process information about your medications and your medication intake. This is necessary in order to provide you with the best possible experience and manage your dosing schedule.

Tap "I consent" to approve and proceed to the next step. You can learn more about how your data is handled by tapping the "Privacy Policy" link.

3.4.3 Create account

If you're using an Android device, you can sign up either through your Google Account or with your email and password. If you use an iPhone, there are the same options as well as the ability to use your Apple account.

If you choose to register with email and password, you will need to verify your email address. You'll receive an email with a verification code that you'll need to enter in the app in order to continue.

3.4.4 Create your dosing schedule

In this step, enter your daily dosing schedule into the app. Because the app allows you to do this yourself, it is important that you take responsibility for following your doctor's prescription.

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If your doctor has given you a paper copy of your schedule, select “Yes, I have” when asked if you have received a schedule from your doctor in order to add the schedule to the app by taking a photo of it. Then follow these instructions:

1. If this is the first time the app uses the camera, you need to start by allowing the app to use the camera.
2. Then allow the app to process data in images.
3. Take a photo of the paper with your schedule, and wait for the app to analyse the image and create your schedule.
4. Carefully review the schedule suggested by the app. Because the AI analysing the images may make mistakes, it is important to check that the times and the number of tablets for each dose are correct.

If you have not received a paper with your schedule or do not want to use the camera

Select “No, I don’t have a schedule” when asked if you have received a schedule from your doctor, and manually create your schedule by following these steps:

1. Click “Add dose” to create your first dose.
2. Enter the time and number of tablets. Then select “Save”.
3. Repeat the process for each dose until you have created your entire prescribed schedule.

Be careful to make sure that the dosing schedule in the app exactly matches the instructions your doctor gave you. You should change your schedule only after consulting your doctor.

3.4.5 Enable notifications

To receive reminders to take your medication, you need to allow the app to send notifications. We strongly recommend that you do this because notifications are an important feature that helps you take your medication in the right dose at the right time.

1. When you are asked if Levilog can send you notifications, you need to select "Allow". If you select "Do not allow", you will not receive any reminders from the app.

If you accidentally select "Do not allow", you can change this in the settings of your phone.

2. If you allow notifications and use an iPhone, you will be asked whether you want your notifications to play audio even when your phone is set to silent. This is recommended so you don't miss any important reminders.
To enable this:
 - a. Select "Yes, always enable notifications".
 - b. Press "Allow" when the phone asks whether you want to allow critical alarms.
3. On the next screen, you can review and edit your notification settings.

3.4.6 Set medication refill reminders

Finally, set medication refill reminders in the "Tablets left" function.

In order for the app to correctly calculate the number of tablets left, it needs to know when you started using your current dose dispenser. This information is used to notify you when it is time to switch to a new dispenser.

If you don't remember when you started using your current dispenser, you can skip this step now. The next time you start a new dispenser, you have the option to add the start date to your "Medication" screen.

3.5 Logging in

If you log out or switch devices, you can log back in to your existing account by selecting "I already have an account" on the welcome screen. Then choose the

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same login method you used to create your account – either Google, Apple (if you're using an iPhone), or email.

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4. How to use Levilog

Use Levilog to get reminders of when to take your medication and to log in to the app after taking your dose.

To navigate the app, click the icons at the bottom of the screen.

4.1 Notifications

You'll get a notification when it's time to take your medication. Tap the notification to open the app and log your dose.

If you do not act on the notification, you may receive a new reminder after 5 and 15 minutes. You choose whether you want these extra reminders when you create your account and can then change these settings in the app at any time.

4.2 Your day

You can access this screen by tapping "Your day" in the menu at the bottom.

On this screen, you can log your scheduled doses. If it is not time to log a dose yet, the time when the next dose should be taken is displayed. You can choose "Log early" if you take this dose before the scheduled time. Doing so will mark it as taken, and you will not receive further notifications for that dose.

At the bottom of the screen is an area where you can record any extra doses you take. To log an extra dose, tap "Log extra dose", and enter the number of tablets you took and when.

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4.3 History

You can access this screen by tapping “History” in the menu at the bottom. The top part of the screen shows the doses you have already logged today. By tapping a dose in the list, you can view and edit details.

When you scroll down, you’ll see an overview of all the doses you’ve ever logged in the app. Click to open a view where you can see insights such as “average daily dosage”. To see details about a specific day, tap that day.

4.4 Medication

You can reach this screen by tapping “Medication” in the bottom menu. Here are several features that facilitate the management of your medication.

- **Your medication schedule**

Here you will see the times and doses of your scheduled medication intake. If you need to make changes, you can tap “Change schedule”. Change your schedule only as prescribed by your doctor.

- **Tablets left**

Here you can see an estimate of how many tablets you have left in your dose dispenser. When it’s time to start a new dispenser, you can register it by tapping “Start new”

- **How to use your dispenser**

Here is guidance on how to handle your dispenser. Tap “See instruction” for detailed information.

- **Sound signal in silent mode**

If you are using an iPhone and have chosen to receive reminders with sound even when your phone is set to silent, you can temporarily turn off the sound here.

4.5 Settings

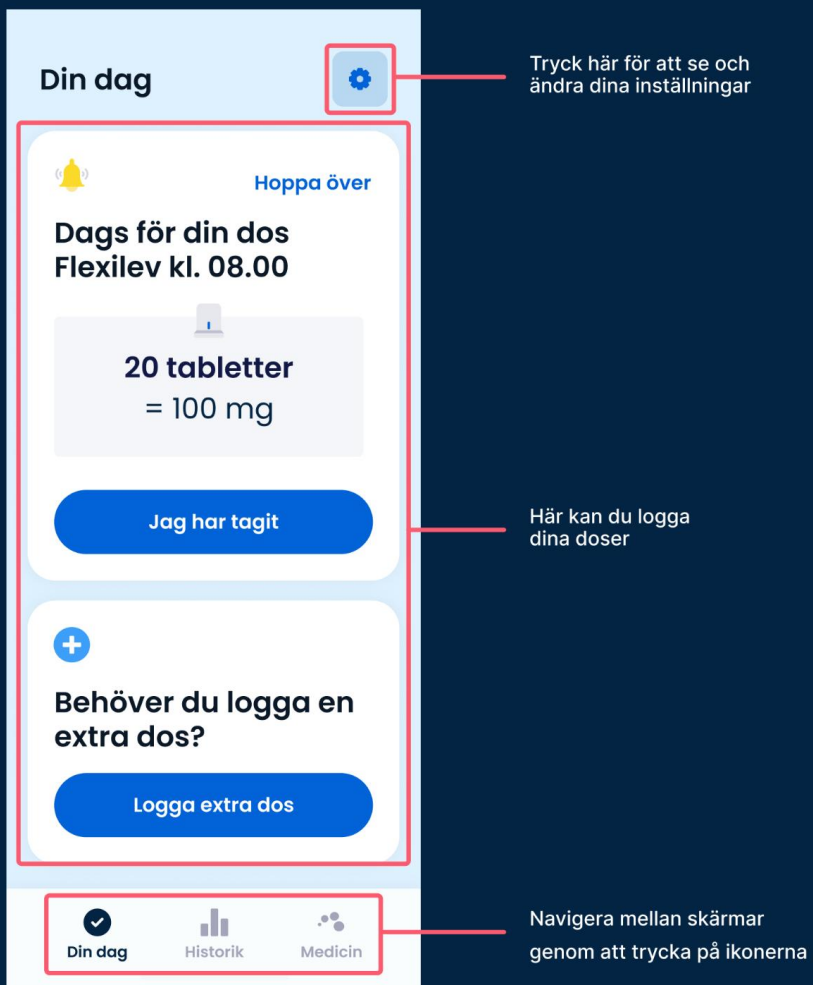
In the upper corner of each screen there is a small gear wheel symbol. Pressing it will take you to the app settings. There you will find settings for notifications, options to contact technical support, and information about the app (including the labelling of the app and a link to this instructions for use) as well as your user agreement and consents. You can also change settings for your account (e.g. email address, or password) as well as log out or delete your account. NOTE: If you choose to delete your account, all of your logged-in data will be deleted, and the account cannot be restored.

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4.6 How often should you use Levilog?

Open Levilog at least once a day when your phone has an internet connection. This is necessary for the app to schedule notifications for the coming days and continue sending reminders.

Levilog works best if you record your doses carefully. Be sure to log each time you take your medication – both your scheduled and extra doses. This gives you a complete history of your medication intake and ensures that the estimate of “Tablets left” is correct.

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5. Technical support

5.1 Contact support

If you encounter technical problems, feel insecure, or discover something that doesn't seem right, click on the gear wheel symbol at the top of the "Your Day", "History", or "Medication" screens. Browse the list and select "Contact support" to send an email to the support team. They will assist you further. You can expect a reply on the next working day after you've sent your request.

If you cannot access the app, you can also reach the support team by emailing levilogsupport@navamedic.com.

5.2 Reset password.

If you have forgotten your password, click "Forgot password?" on the login page and enter your email address. When you receive an email (check your spam folder if it takes longer), copy the verification code and return to the app to choose a new password.

If you can't access the app, email us at levilogsupport@navamedic.com.

5.3 Print instructions for use

The instructions for use is provided in a printable format. Select the printer function in your browser.

You can also request the instructions for use in paper form by sending an email request to levilogsupport@navamedic.com. The instructions for use will be sent by post within one week at no extra cost.

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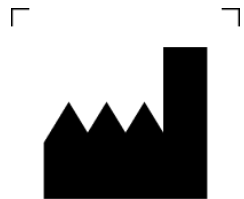
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6. Glossary of ISO symbols

The symbols used in this app follow the EN-ISO 15223-1: 2021 standard, thereby ensuring the clear and consistent communication of medical information.



Manufacturer



Date of manufacture



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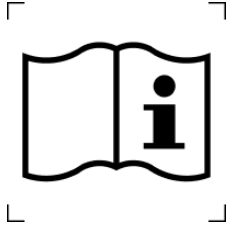
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Unique device identification



Consult instructions for use

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7. Contact information

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433 63 Sävedalen
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info@navamedic.com

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