

9.50 cm

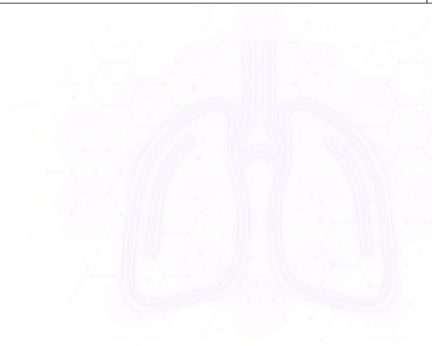


INSTRUCTION MANUAL



eLUPIHALER

12.50 cm



CONTENTS

About eLupihaler	1
Why is eLupihaler important to you?	2
How does eLupihaler help to improve adherence?	2
How does eLupihaler help improve respiratory conditions?	2
eLupihaler Components	3
Unboxing eLupihaler	4
eLupihaler Setup	5
Connecting to the Mobile Application	17
Turning on the device	26
Medication Schedule Management	28
How to take medicine with eLupihaler	35
Adding a Caregiver	51
Caregiver Flow	55
Battery life	64
Safety Precautions	64
Symbols used	65
Warnings	66
Important Note	66

ABOUT ELUPIHALER

- The eLupihaler is a smart, Bluetooth-enabled dry powder inhaler.
- The inhaler records the date and time you take your medication and the technique – how deep and how long you inhale.
- A mobile app, compatible with Android OS version 7.0 and above and Apple iOS 16.0 (iPhone 12 and above), allows you to transfer the recordings to your smartphone for review. Your caregiver and the doctor can also be allowed to assess the information.
- Visual indications are provided on the device during the operation, with two LEDs. They guide you with the proper sequence of inhalation.
- With the eLupihaler mobile app, you can get daily dose reminders to help you take your medication as prescribed by your doctor.
- Based on your current location, with real-time updates on weather conditions, humidity, air quality index, and temperature get displayed on the mobile app which can help you be prepared with rescue medication.
- The mobile app provides a complete usage report on a daily/weekly, or monthly basis, allowing you to track your DPI usage.

WHY IS ELUPIHALER IMPORTANT TO YOU?

- With eLupihaler, maintaining consistency in your treatment is simple, providing you with timely relief.
- Better adherence can also prevent disease progression & help improve your quality of life.

HOW DOES ELUPIHALER HELP TO IMPROVE ADHERENCE?

- The eLupihaler app provides a reminder/notification to take DPI on time, as per the dosage frequency (once /twice a day, etc.) prescribed by your doctor.
- The eLupihaler app shows the number of dosages consumed from your current DPI device.

HOW DOES ELUPIHALER HELP IMPROVE RESPIRATORY CONDITIONS?

- Inhalation data gets captured, stored and then transferred to the mobile app to measure the quality of inhalation. Through color codes, descriptive texts and graphs, mobile application generates reports for the user to understand and to improve the inhalation technique and hence potentially improving the medication effectiveness.

ELUPIHALER COMPONENTS



**DPI CAPSULE GOES
HERA**



UNBOXING ELUPIHALER



- Hold the box upright and carefully unbox the device from the middle



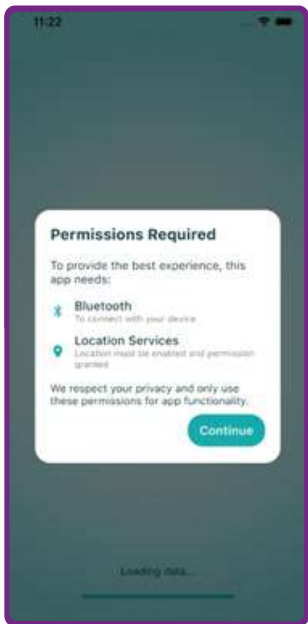
- Scan the QR code on left side to download eLupihaler application

ELUPIHALER SETUP



- **Welcome Screen** of the eLupihaler takes a few seconds to initialize for the first time.

ELUPIHALER SETUP



- Click on **Continue** as device requires Bluetooth permissions to exchange data.
- Location access is required to provide accurate air quality parameters of your current location.

ELUPIHALER SETUP



- Please click on **I Understand & Continue** button once you have read all the instructions.

ELUPIHALER SETUP



4:27

Welcome to eLupihaler

Enter your mobile number and we will send you a verification code.

+91 Enter phone number

☐ *By Checking this box you have agreed to our Terms and Conditions

Continue

- Please enter your mobile number and click on the Checkbox after reading and agreeing to the **Terms & Conditions.**

ELUPIHALER SETUP



11:23

Please enter the OTP we have sent on
+910000000013

Enter OTP

Submit

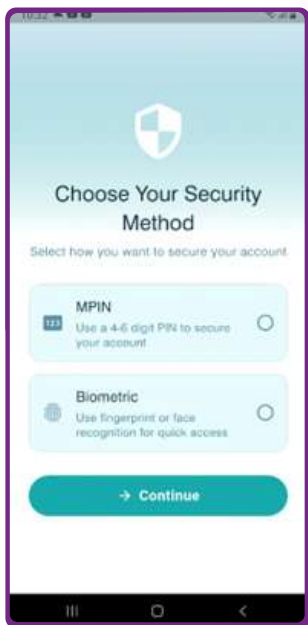
Change Number?

or

You can resend OTP in (47) seconds

- Enter the OTP received in SMS and click on **Submit** button OR request for **Resend OTP** if you haven't received any (after a 60 second countdown).

ELUPIHALER SETUP



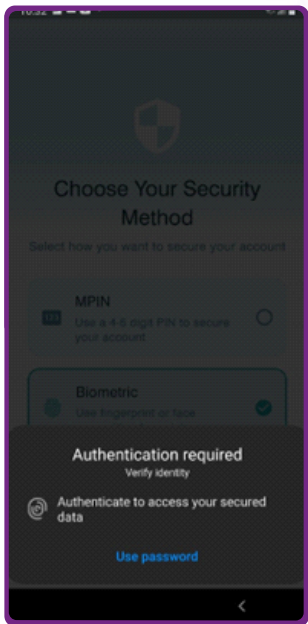
- For future access to the application and to protect it from unauthorized use, you can set a 4-digit **MPIN** or enable **biometric** authentication

ELUPIHALER SETUP



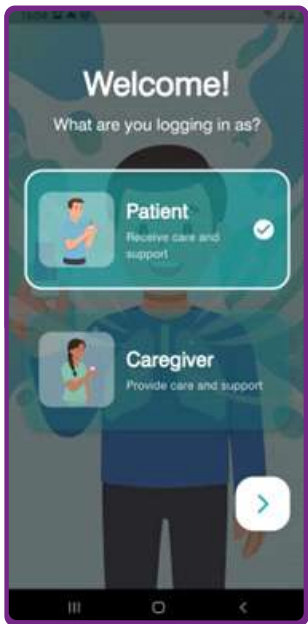
- Set and confirm 4 digit MPIN if you have chosen MPIN option

ELUPIHALER SETUP



- Confirm or authorize biometric authentication (configured at the device level) to be used for eLupihaler.

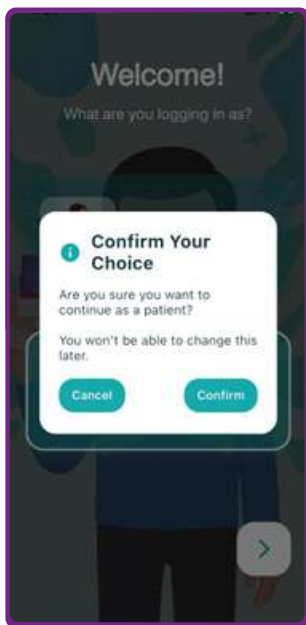
ELUPIHALER SETUP



- Please select your role as a **Patient** or **Caregiver**.
- For **Patient** role, click on the Patient icon and click on > **button** to continue.

For Caregiver role, select the Caregiver role by clicking on caregiver icon and click on > **button** to continue. Please refer to **Caregiver Flow** section for subsequent instruction details.

ELUPIHALER SETUP



- Please confirm your selection.

ELUPIHALER SETUP



- Click on **continue** (> button) to manage your basic profile details.

ELUPIHALER SETUP



10:15 100%

← Patient Details

Please enter your basic details



 Enter your full name

Select your gender

Male ♂ Female ♀

Date of Birth

 Fri, Feb 22, 2008

Feet Inches

Weight

Next

- Please complete your profile by filling basic details like name, gender etc.

CONNECTING TO THE MOBILE APPLICATION

Next set of screens will guide you to connect eLupihaler to mobile application for the first time.



- Remove the white section reveal the eLupihaler inside the tray

CONNECTING TO THE MOBILE APPLICATION

Next set of screens will guide you to connect eLupihaler to mobile application for the first time.



- Pull out the inhaler from the tray by holding the inhaler carefully as shown.

CONNECTING TO THE MOBILE APPLICATION

Next set of screens will guide you to connect eLupihaler to mobile application for the first time.



- Hold the inhaler with the power-indicator LED facing you while using the device.

CONNECTING TO THE MOBILE APPLICATION

Next set of screens will guide you to connect eLupihaler to mobile application for the first time.



- Turn on device battery – **Tilt** the device and **push** the button cover gently, till it clicks into the main device firmly.

CONNECTING TO THE MOBILE APPLICATION

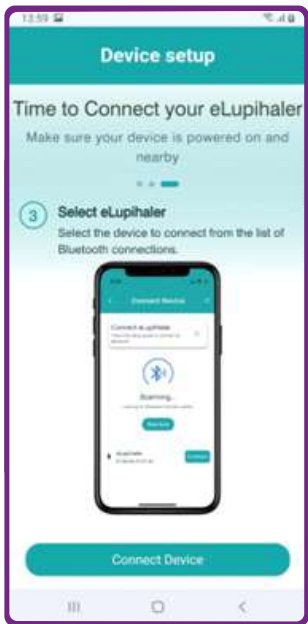
Next set of screens will guide you to connect eLupihaler to mobile application for the first time.



- Once the device turns on, blue LED keeps blinking for every **2 seconds** till the device gets paired.

CONNECTING TO THE MOBILE APPLICATION

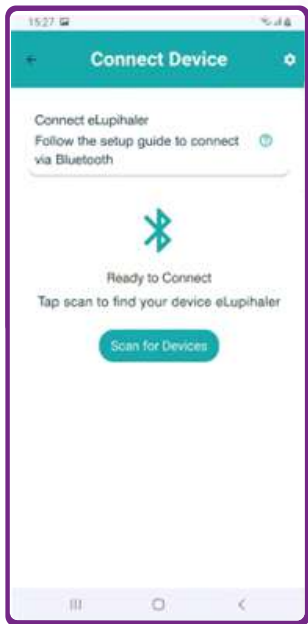
Next set of screens will guide you to connect eLupihaler to mobile application for the first time.



- Time to connect to the device via Bluetooth by clicking on **Connect Device**.

CONNECTING TO THE MOBILE APPLICATION

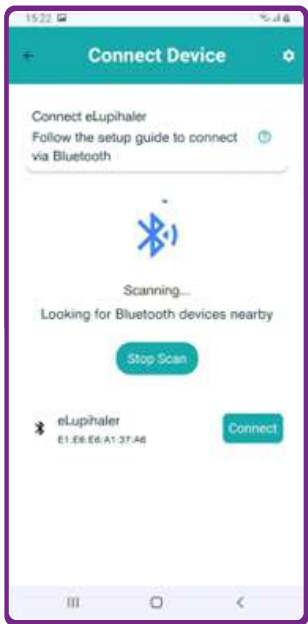
Next set of screens will guide you to connect eLupihaler to mobile application for the first time.



- Click on the **Scan for Devices** to scan for eLupihaler devices.

CONNECTING TO THE MOBILE APPLICATION

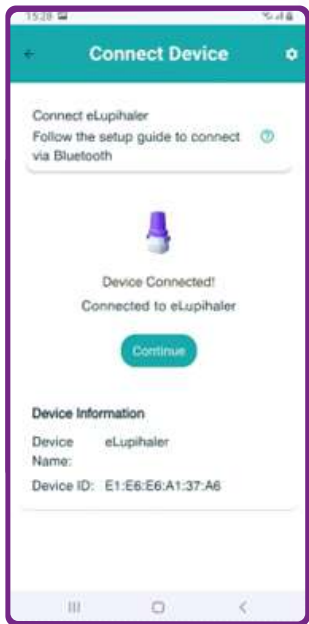
Next set of screens will guide you to connect eLupihaler to mobile application for the first time.



- Click on the device from the scanned eLupihaler devices list to connect/pair with the device.
- If your device isn't listed, check your device for blinking blue lights. If you don't see any blue lights, please refer to **Turning on the device** section.

CONNECTING TO THE MOBILE APPLICATION

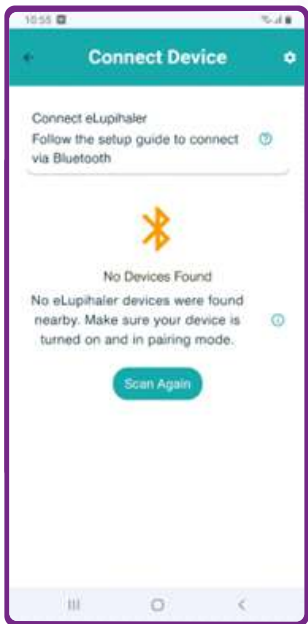
Next set of screens will guide you to connect eLupihaler to mobile application for the first time.



- Once device is successfully paired you will get confirmation on the screen displaying all device specific details.
- Device setup is now completed, and you are all set to manage your Medication schedule.

TURNING ON THE DEVICE

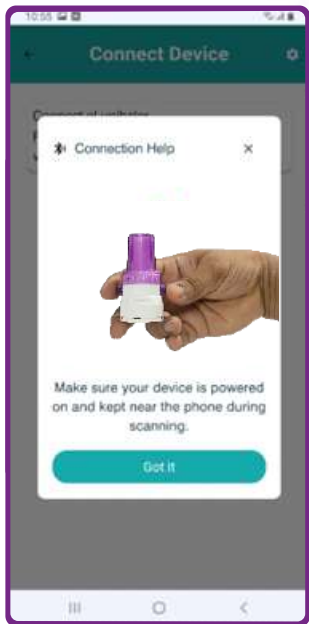
Next set of screens will guide you to connect device to mobile application if you weren't able to connect during the initial setup process.



- While scanning for the devices, if you encounter a scenario where application couldn't list any eLupihaler devices, click on the icon before clicking on **Scan again**.

TURNING ON THE DEVICE

Next set of screens will guide you to connect device to mobile application if you weren't able to connect during the initial setup process.



- You will get **Help** screen popup to guide you through the process

MEDICATION SCHEDULE MANAGEMENT

You will be able to add or modify medication and its schedule as per prescription.

ADD MEDICATION



- Begin to add your medications.

MEDICATION SCHEDULE MANAGEMENT



- You can search for a specific medicine, view additional medicine details by clicking on > **button** next to the listed medicines.

MEDICATION SCHEDULE MANAGEMENT



14:04

Select Regimen

Budamate 100



Time to take medicine

Morning
7AM - 12PM

Afternoon
12PM - 5PM

Evening
5PM - 12AM

How many Capsules are prescribed ?

Morning: ☐ ☐

Afternoon: ☐ ☐

Save

- You can select **Morning**, **Afternoon** or **Evening** as per your prescription along with the dosage information.

MEDICATION SCHEDULE MANAGEMENT



Do you take any other
DPI in your daily
medication?

Stay on track with your medication schedule

Add DPI

» No, I don't take any other DPI

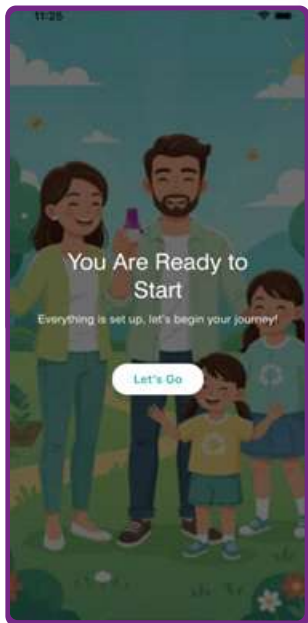
- Click on **Add DPI** if you have more medications to include (as per your prescription).
- Click on **No, I don't have any other DPI** if you have completed your medication profile

MEDICATION SCHEDULE MANAGEMENT



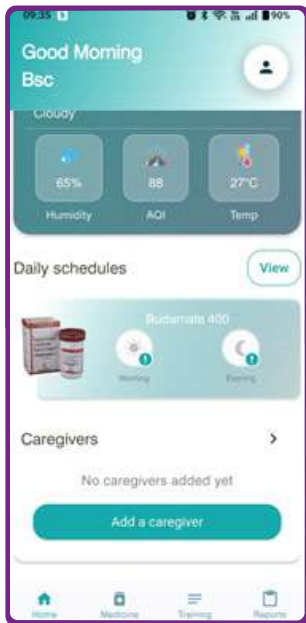
- You can also set reminders in the app to get alerts/ reminders on medication schedule.

MEDICATION SCHEDULE MANAGEMENT



- Once all medications are saved in your profile, click on **Let's Go**

MEDICATION SCHEDULE MANAGEMENT



- You will be navigated to application's home screen.

HOW TO TAKE MEDICINE WITH ELUPIHALER

After successfully connecting with the device, you can use the inhaler with or without the mobile application by following steps below.



- Remove the protection cap from the Inhaler and hold the inhaler with power indicator or LED facing you.



- Hold the base of the inhaler firmly and open the inhaler by turning the mouthpiece in the direction of the arrows.



- Take a capsule and place it in the inhaler's capsule chamber.
- Check whether the capsule is completely inside the capsule chamber.
- If not, put the capsule in correctly

HOW TO TAKE MEDICINE WITH ELUPIHALER

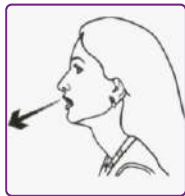


- Close the inhaler by turning the mouthpiece back to the closed position



- Hold the inhaler upright (with the mouthpiece upwards), hold the push buttons between thumb and index finger. Hold the inhaler with power indicator or LED facing you.

- Use both fingers at the same time to press these buttons once, using quick, firm pressure. The capsule is now evenly punctured.



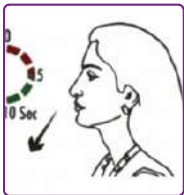
- Both the LEDs on the device start to blink slowly. At this stage, if you have a mobile phone handy, you can scan and pair the device for real-time inhalation tracking.
- This is an indication to empty your lungs, preparing for the inhalation.
- Hold the device a little away from your mouth and, while observing the LED blinking, breathe out gently and empty your lungs.

HOW TO TAKE MEDICINE WITH ELUPIHALER

- Once the lungs are emptied, bring the inhaler close to your mouth, hold it horizontally.
- Tilt your head back slightly.

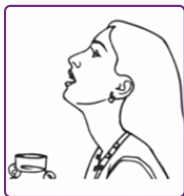


- Insert the mouthpiece of the inhaler completely into your mouth, behind your teeth, and on your tongue.
- Close your lips tightly around the mouthpiece.
- Breathe in rapidly but steadily, as deeply as you can.
- The inhaler makes a rattling noise if it is operating properly, as the capsule spins in the chamber to disperse the powder.



- Remove the inhaler from your mouth. Hold your breath for about **5-10 seconds** so that your lungs can take up the medication. Breathe out gently. Open the inhaler and check whether the capsule is empty; if not, repeat the inhalation.

HOW TO TAKE MEDICINE WITH ELUPIHALER



- After completion of the inhalation, rinse your mouth with water; do not swallow. Open the inhaler and remove the empty capsule. Put the protection cap back on the inhaler.

• Syncing Data:

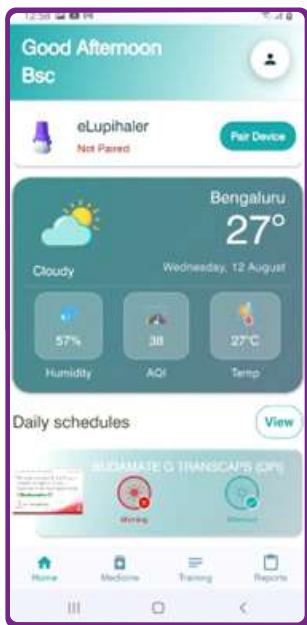
- Inhaler, when connected to eLupihaler application on your Mobile, automatically synchronizes the data.



• Cleaning the inhaler:

- Do not wash or put any part of your eLupihaler in water. eLupihaler contains powder and must always be kept clean and dry.
- If the mouthpiece needs cleaning, gently wipe it with a dry cloth or tissue.

Let's see your first inhalation in eLupihaler app, follow the steps in How to take medicine in eLupihaler to administer a medication.



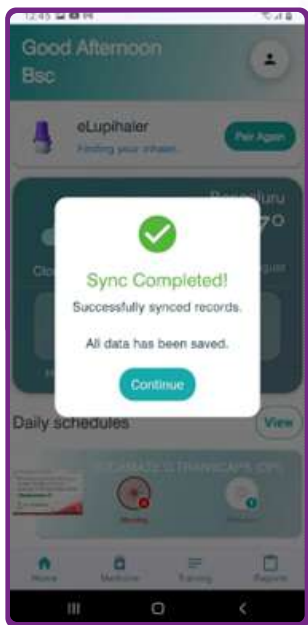
- Open the app on your mobile and click on **Pair device** on home screen to synchronize your **Inhalation data**.
- **Note:** At the inhaler end, to pair device please press the side pins and connect your device with app.

Let's see your first inhalation in eLupihaler app, follow the steps in How to take medicine in eLupihaler to administer a medication.



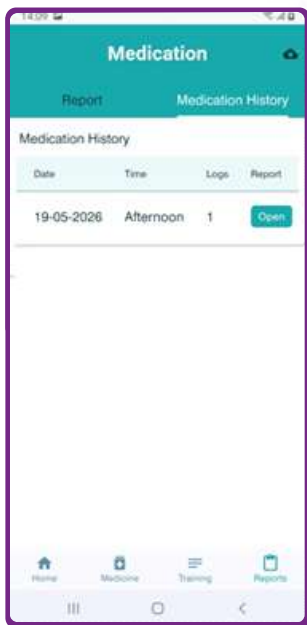
- Synchronization of the inhalation data gets triggered automatically as shown.
- Note: Depending upon the number of un-synchronized inhalations, it may take few seconds to complete the process. Synchronization progress gets displayed.

Let's see your first inhalation in eLupihaler app, follow the steps in How to take medicine in eLupihaler to administer a medication.



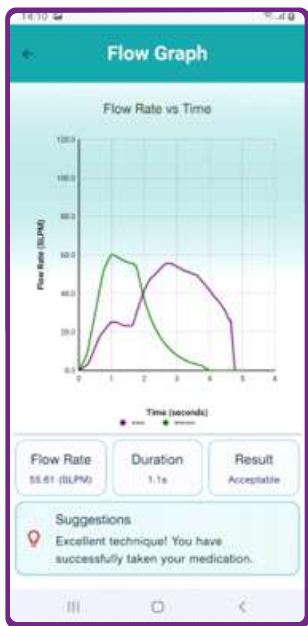
- Confirmation message gets displayed at the end of the process. You can click on **Continue** button to proceed.

Let's see your first inhalation in eLupihaler app, follow the steps in How to take medicine in eLupihaler to administer a medication.



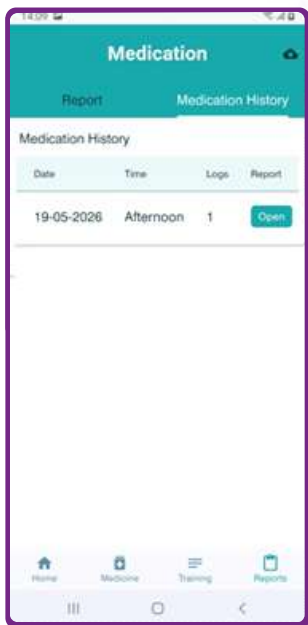
- Clicking on **Continue** button, medication history gets listed.
- You can click on **Open** button to view details around the inhalation data.

Let's see your first inhalation in eLupihaler app, follow the steps in How to take medicine in eLupihaler to administer a medication.



- Inhalation data gets displayed as **Flow Rate vs Time** graph, which helps you analyze and compare your breathing technique vs recommendation.
- Report will also display **Flow rate, Duration** and qualitative grating on the overall result along with any **Suggestions** to improve the effectiveness.

Let's see your first inhalation in eLupihaler app, follow the steps in How to take medicine in eLupihaler to administer a medication.



- Clicking on **Continue** button, medication history gets listed.
- You can click on **Open** button to view details around the inhalation data.

VIEWING OF INHALATION REPORTS

Your inhalation data collected through the device gets stored in the mobile application and gets displayed across multiple sections of the application. These sets of instructions will help you locate, view and generate reports which can be shared with others in PDF format.



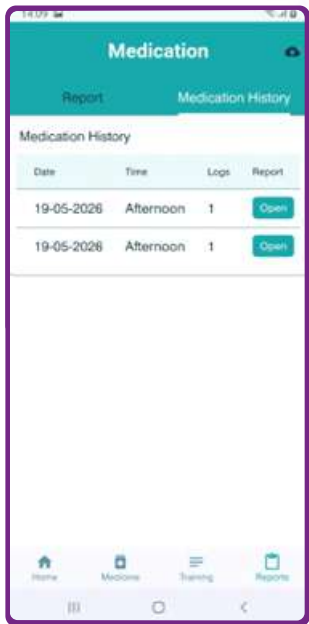
- On your Home screen, medication adherence history gets displayed across multiple sections.
- Adherence is displayed in a graphical (fuel gauge) format along with numeric breakdown.

VIEWING OF INHALATION REPORTS



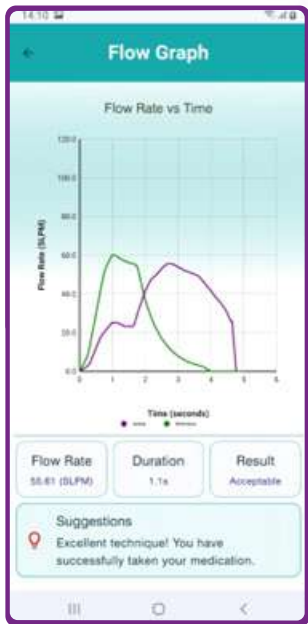
- Adherence can also be viewed in a calendar format with indicators on **Missed**, **On Time** and **Upcoming**.

VIEWING OF INHALATION REPORTS



- Clicking on **Report** button, medication history gets listed.
- You can click on individual report's **Open** button to view details around the inhalation data

VIEWING OF INHALATION REPORTS



- Inhalation data gets displayed as **Flow Rate** vs **Time** graph, which helps you analyze and compare your breathing technique vs recommendation.
- Report will also display **Flow rate, Duration** and qualitative grading on the overall result along with any **Suggestions** to improve the effectiveness

EDIT REGIMEN



Select Regimen

Budamate 100



Time to take medicine

Morning
7AM - 12PM

Afternoon
12PM - 5PM

Evening
5PM - 12AM

How many Capsules are prescribed ?

Morning Afternoon

☒ ☐ ☒ ☐

Save

- To modify the regimen, click on the medication from your profile.
- Note: Refer to **Add Medicine** flow if you are adding a new medication.

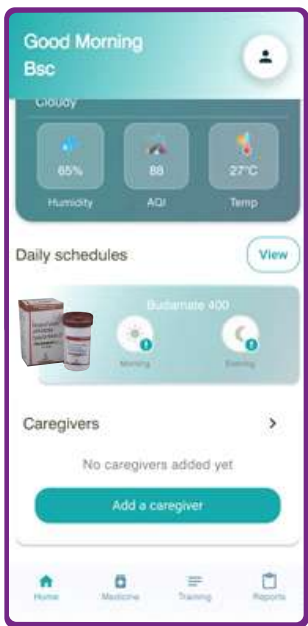
EDIT REGIMEN



- You can modify the schedule by clicking on **Morning, Afternoon, Evening.**
- You can also set the dosage (single or multiple) dose for each schedule.

ADDING A CAREGIVER

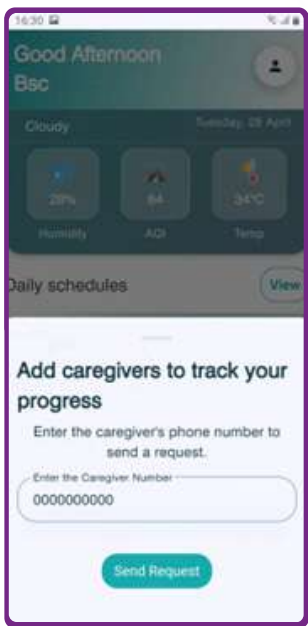
Application allows you to add either a care provider or a family member in a **Caregiver** role to your profile. Simply follow these steps to add them. They will be able to monitor your medication records/history to support your health



- At the bottom of the home screen, you will find a Caregiver section. To add a care giver, please click on **Add a caregiver** button.

ADDING A CAREGIVER

Application allows you to add either a care provider or a family member in a **Caregiver** role to your profile. Simply follow these steps to add them. They will be able to monitor your medication records/history to support your health



16:30

Good Afternoon
Bsc

Cloudy Tuesday, 22 April

28% Humidity 84 AQI 34°C Temp

Daily schedules [View](#)

Add caregivers to track your progress

Enter the caregiver's phone number to send a request.

Enter the Caregiver Number

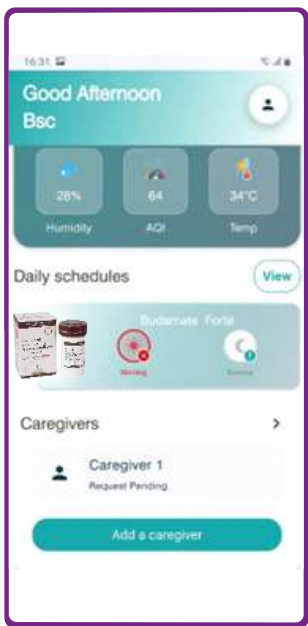
0000000000

[Send Request](#)

- You will be prompted to provide caregiver's mobile number to initiate the request.

ADDING A CAREGIVER

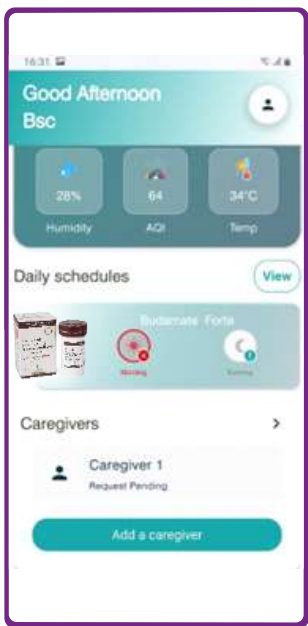
Application allows you to add either a care provider or a family member in a **Caregiver** role to your profile. Simply follow these steps to add them. They will be able to monitor your medication records/history to support your health



- You will be able to monitor the status of the request under the Caregivers section

ADDING A CAREGIVER

Application allows you to add either a care provider or a family member in a **Caregiver** role to your profile. Simply follow these steps to add them. They will be able to monitor your medication records/history to support your health



- Once request gets approved successfully, you will see the Caregiver details.
- You will be able to add one or more Caregivers as per your needs.
- You can also **delete or disassociate** a specific Caregiver by clicking on delete button

CAREGIVER FLOW

If you have chosen a **Caregiver** role during onboarding, follow these steps to understand the flow.



- Please select your role as a **Patient** or **Caregiver**.
- For **Caregiver** role refer to **Caregiver Flow** section

CAREGIVER FLOW

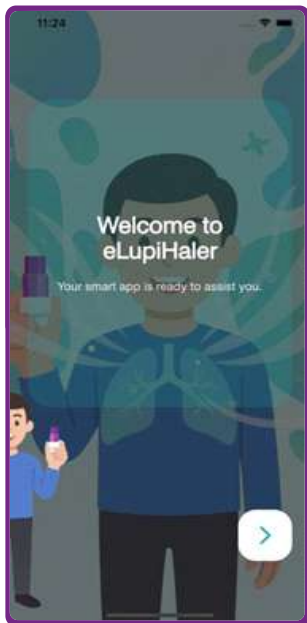
If you have chosen a **Caregiver** role during onboarding, follow these steps to understand the flow.



- Confirm your selection as **Caregiver**.

CAREGIVER FLOW

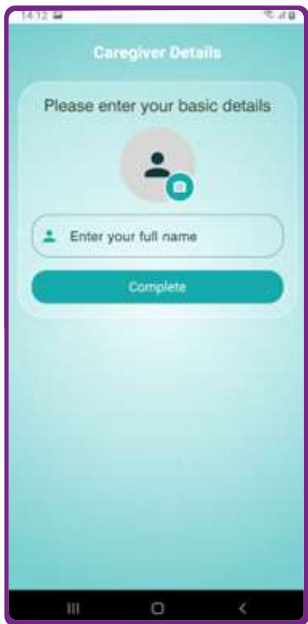
If you have chosen a **Caregiver** role during onboarding, follow these steps to understand the flow.



- Click on continue (> button) to manage your basic profile details.

CAREGIVER FLOW

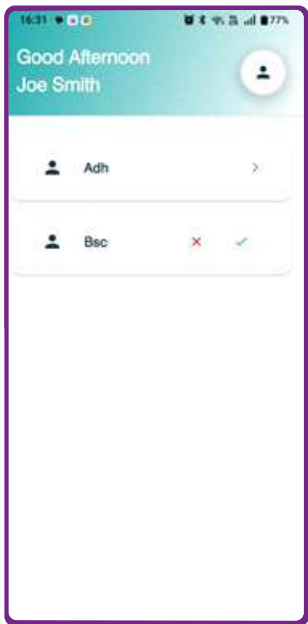
If you have chosen a **Caregiver** role during onboarding, follow these steps to understand the flow.

A screenshot of a mobile application interface titled "Caregiver Details". The screen has a light blue background. At the top, the title "Caregiver Details" is displayed. Below the title, there is a prompt: "Please enter your basic details:". Underneath the prompt is a circular icon containing a person silhouette and a speech bubble. Below the icon is a text input field with a person icon on the left and the placeholder text "Enter your full name". At the bottom of the input area is a teal-colored button labeled "Complete". The mobile phone's status bar at the top shows the time "14:12" and various icons. The Android navigation bar is visible at the bottom.

- Please complete your profile by providing your name.

CAREGIVER FLOW

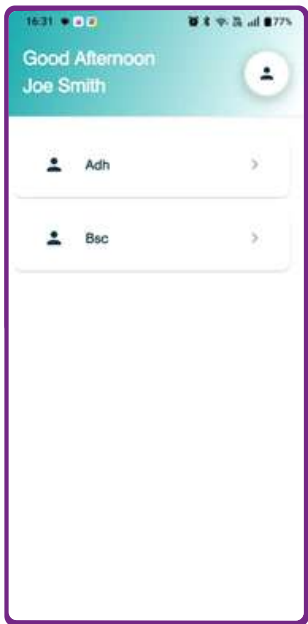
If you have chosen a **Caregiver** role during onboarding, follow these steps to understand the flow.



- After successful registration under **Caregiver** role, you will be navigated to a screen listing all individuals who have mapped you as a Caregiver.
- You will be able to **Approve** or **Reject** individual requests.

CAREGIVER FLOW

If you have chosen a **Caregiver** role during onboarding, follow these steps to understand the flow.



- Once Approved, by clicking on the > button, you will be able to view medicine and medication history details for selected individuals.

CAREGIVER FLOW

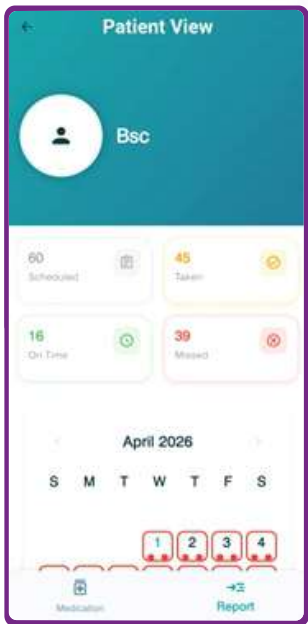
If you have chosen a **Caregiver** role during onboarding, follow these steps to understand the flow.



- On clicking the patient record, you will be navigated to **Patient View**

CAREGIVER FLOW

If you have chosen a **Caregiver** role during onboarding, follow these steps to understand the flow.



- Scroll down to see some of the statistics associated with the patient.

CAREGIVER FLOW

If you have chosen a **Caregiver** role during onboarding, follow these steps to understand the flow.



- Scroll down further to see adherence and inhalation quality details in a monthly calendar view for selected patients.

BATTERY LIFE

- One non-replaceable battery supports up to a maximum of 600 puffs, which represents the total usable life of the device.

SAFETY PRECAUTIONS

- Do not use the device near explosive substances.
- Do not use the device in environments with high dust and vibration levels.
- Do not place units near heat sources.
- Store the device in a dry place.
- eLupihaler contains a lithium battery and should dispose of it after using it according to local regulations.

1.1. Environmental Conditions:

Temperature range: 10°C to 40°C.

Relative humidity range: 20% to 90%.

Atmospheric pressure range: 600 mBar to 1060 mBar.

The device is intended to operate at an altitude $\leq 2,000$ m.

1.2. Storage:

Temperature range: 5°C to 40°C.

Relative humidity range: 5% to 95%.

1.3. Transportability.

Temperature range: 5°C to 40°C.

Relative humidity range: 5% to 95%.

SYMBOLS USED



Accompanied by a date, this symbol indicates the device's manufacturing date



This symbol instructs the user to consult the device's instructions for proper usage information



Refers to the legal Manufacturer (Lupin Limited)



Serial Number. The device's serial number should accompany the symbol.



General Warning Sign



Batch Code



Ingress Protection

IP2X: Protected against solid objects over 12.5mm IPX1: Protected against vertically falling drops of water



Drug use in ML



Keep away from the rain



Fragile, handle with care



Temperature Limitation



Humidity Limitation



Do not use if the package is damaged



Use by date

WARNINGS

- Handle the eLupihaler device carefully. Ensure that it does not fall. Falling might damage the device.

IMPORTANT NOTE

- Do not try to disassemble the eLupihaler device.
- One eLupihaler device can be connected to one mobile only.
- The user will have to get a new device once the battery is discharged.
- If the device does not connect with the mobile phone app, it could be due to a low battery level. If the blue and green lights blink alternately when you press the buttons, it shows this condition.

COMPLIANCE REQUIREMENTS

REFERENCE STANDARDS:

IEC 60601-1: Medical Devices: General Requirements for Safety and Essential Performance.

IEC 60601-1-2: Medical Devices: Collateral Standard: Electromagnetic Compatibility.

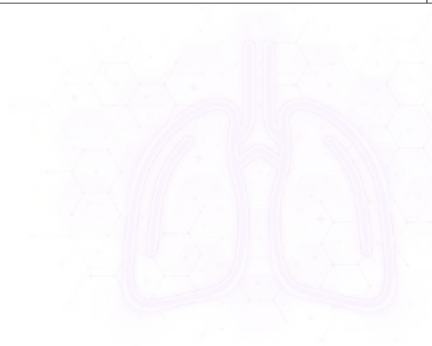
IEC 62304: Medical Devices – Software Life Cycle Processes.

ISO 14971: Medical Devices – Application of Risk Management to Medical Devices.

ISO 13485: Medical Devices – Quality Management System.

ELECTROMAGNETIC COMPATIBILITY: IEC 60601-1-2: 2014

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL
Electrostatic discharge (ESD) IEC 61000-4-2	$\pm 8\text{ kV}$ (contact discharge), $\pm 2\text{ kV}$, $\pm 4\text{ kV}$, $\pm 8\text{ kV}$, $\pm 15\text{ kV}$ (air discharge)	$\pm 8\text{ kV}$ (contact discharge), $\pm 2\text{ kV}$, $\pm 4\text{ kV}$, $\pm 8\text{ kV}$, $\pm 15\text{ kV}$ (air discharge)
RF Radiated Immunity IEC 61000-4-3	3 V/m (10V/m Home Healthcare) at 80 – 2,700MHz, AM Modulation.	3 V/m (10V/m Home Healthcare) at 80 – 2,700MHz, AM Modulation.
Power frequency Magnetic Field (PFMF) IEC 61000-4-8	30 A/m	30 A/m





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