

Intended use

Indication for use

The Mallya device for pen injector is indicated for the capture and wireless transmission of dosing information from compatible Novo Nordisk® FlexPro® pen injectors.

Device features

Mallya is able to:

- record the increment injected by Novo Nordisk® FlexPro® pen (growth hormone dose)
- record the timestamp (date & time) of each injection,
- transmit information relating to dose, time, and date of each injection to a mobile app on a smartphone, when the device is connected to it, using Bluetooth technology.

Clinical environment

The Mallya device for pen injector is intended to be used by patients in the same use environment as their compatible pen injector. There are no known contraindications to the use of Mallya for these patients.

Note: Mallya is compatible with Novo Nordisk® FlexPro® and Sogroya® pen injectors. The list of all the compatible pen injectors is available in Mallya device technical note online at <https://my-mallya.com/>

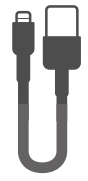
Package contents

Mallya
x1



PN : 0274345

USB cable
x1

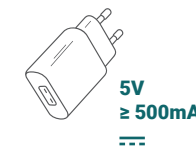


PN : 0373707

User
instructions
x1

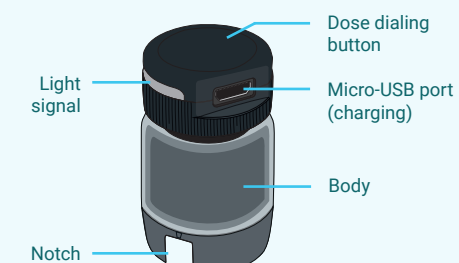


NOTE: the USB charger is not included. Use a Class II USB wall charger, with output 5V and at least 500mA.



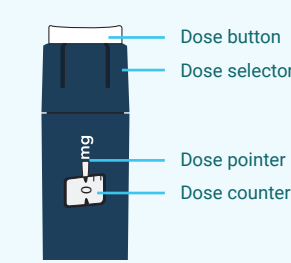
5V
≥ 500mA

Getting to know Mallya and the pen



Mallya

All exterior plastic parts to the device constitutes its applied part



Novo Nordisk FlexPro® pen injector



USER MANUAL

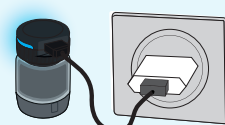
ENGLISH

Getting started

1 Wake up and charge Mallya

Mallya is turned off when it is shipped. You will need to wake it up and make sure it is charged enough before use.

- 1.1. Connect Mallya to the supplied USB cable.
- 1.2. Connect the cable to a powered USB wall charger.
- 1.3. Let the device charge for at least 10 minutes before its first use.
- 1.4. Unplug the cable and Mallya, then unplug the charger.



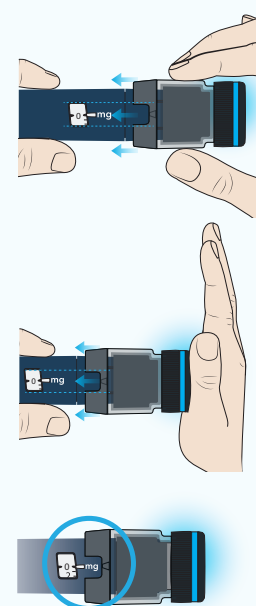
10 min



The **blue** light signal indicates that the device is not paired yet.

2 Assemble Mallya on the pen

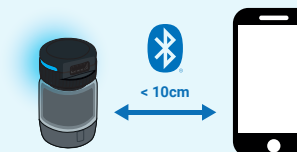
- 2.1. Hold the pen with one hand, keeping the dose button accessible, and protect the needle with the pen cap (if already mounted).
- 2.2. With your other hand, hold Mallya by the Body, without pressing on its dose dialing button.
- 2.3. Insert Mallya on the pen dose button, aligning the Notch of Mallya with the pen Dose counter.
- 2.4. Push Mallya fully onto the pen, pressing the button with the palm of your hand. It must be inserted all the way onto the dose selector.
- 2.5. Make sure Mallya is properly mounted on the pen as shown on the picture.



3 Download a mobile App and pair Mallya

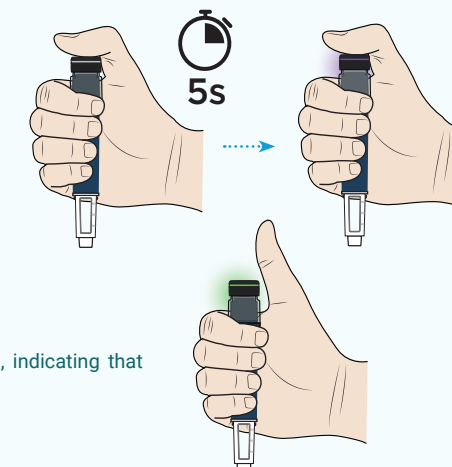
Before you can use your Mallya, you will need to pair it with a mobile application.

- 3.1. Please refer to Mallya internet website <https://my-mallya.com>, or by scanning this QR Code.
- 3.2. Download a compatible application to your smart device on Google Play™ (Android) or the App Store® (Apple).
- 3.3. Activate the Bluetooth on your smartphone, if not already done.
- 3.4. Keep Mallya less than 10 cm away from your smartphone.
- 3.5. Open the App and follow the instructions to pair Mallya. Once paired, Mallya light signal turns **green**, then off.
- 3.6. Select the type of pen the device is mounted on in the App.



4 Activate Mallya

- 4.1. Press firmly on Mallya button for 5 seconds, until its light turns purple.



- 4.2. Lift your finger, Mallya light turns **green**, indicating that Mallya is ready to be used.

NOTE: If Mallya light does not turn **green**, make sure Mallya is sufficiently inserted on your pen. Repeat step 2.4 to push Mallya onto your pen to fully insert it. Then proceed to activate it, following the instructions in step 4.1.

Mallya is now ready for use. Follow the instructions in the next section «Using Mallya».

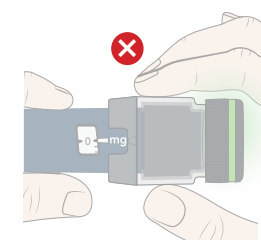
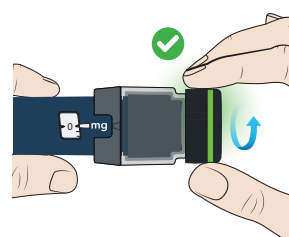
Using Mallya

Refer to the Instructions for Use of your pen for the flow check and the injection instructions.

Monitor your treatment as instructed by your healthcare provider.

If you have any doubts about your treatment, please consult your healthcare provider.

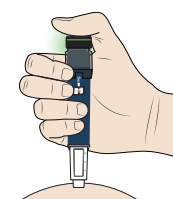
1. Before you start selecting the dose, make sure the pen dose counter shows the number 0. The number 0 should line up in front of the pen dose pointer.
2. Use the Mallya device **black** dose dialing button to select the dose.
3. Turn Mallya button to select the dose you need. The selected dose should line up in front of the pen dose pointer. During a dose selection, Mallya light is **green**.



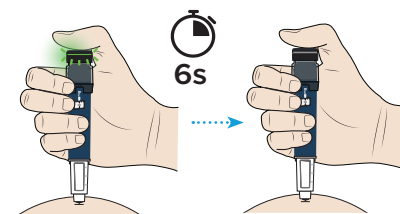
NOTE: Do not use the transparent body of Mallya to select your

dose.

4. Perform the injection as described in the Instructions for Use of your pen injector. Press and hold down the dose dialing button. Watch as the dose counter returns to 0. The 0 must line up with the pen dose pointer. During a dose injection, Mallya light is **green**.

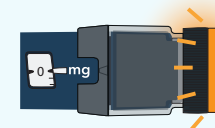


5. At the end of injection, keep the pressure on the button and the needle in your skin until the **green rapid flashing** turns off (6 seconds).



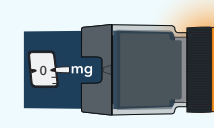
NOTE: Safety tests performed to check the flow, will also be automatically detected, and recorded by Mallya. Perform the safety test to check the flow as described in the Instructions for Use of your pen injector.

Troubleshooting



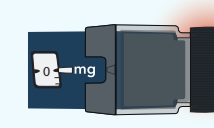
Orange Rapid Flashing

The pen dose counter must be set at 0. When the pen dose pointer is aligned with the number 0, press the dose button for 2 seconds until Mallya light turns **green**.



Orange Solid

Mallya's battery is low. Plug-in and charge your Mallya (2h for a full charge). The light is **orange** during injections if the battery is low.



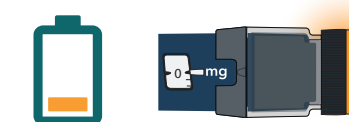
Red Solid

Mallya is in error state. In this state, Mallya is not ready to record injections. Reset your Mallya and restart it. Refer to section «Resetting Mallya». If the problem persists, contact the Support service.

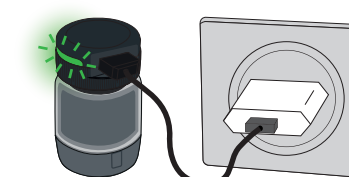
The red signal is not an alarm according to IEC 60601-1-8.

Charging Mallya

Mallya battery has 2 weeks minimum autonomy in normal use conditions. When the battery is low, Mallya light is **orange**.



Connect Mallya to the supplied USB cable, then connect the cable to a powered USB wall charger to charge Mallya. Do not use any other cable.



Please connect the supplied USB cable to the USB port of a power adapter (IEC / UL 60950-1 or IEC / UL 62368-1 certified with CE or UL marking) suitable for your region.

While charging, Mallya light **flashes slowly green**. Mallya does not record injection data while it is charging.

NOTE: When the battery is fully charged, Mallya light turns off (a full charge takes 2 hours).



PLEASE TURN THE PAGE →

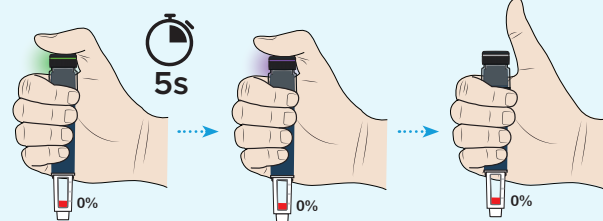
Transferring Mallya to a new pen

Resetting Mallya

1 Deactivate Mallya

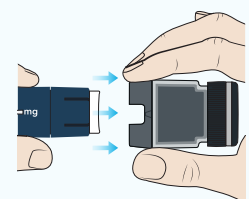
Before transferring Mallya to another pen, you must first deactivate it so that transferring the device won't cause false doses to be logged in the application.

- 1.1. Press firmly on Mallya button for 5 seconds, until its light turns **purple**. Then, lift your finger. Mallya light turns off, indicating that Mallya is deactivate.



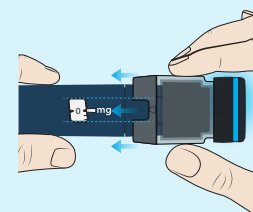
2 Remove Mallya from the pen

- 2.1. Hold Mallya by the body.
- 2.2. Pull Mallya straight off the pen.
- 2.3. Put Mallya down upright on a flat surface, with the button up.

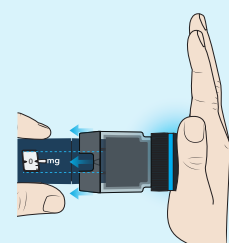


3 Assemble Mallya to the new pen

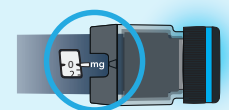
- 3.1. Insert Mallya on the pen dose button, aligning the Notch of Mallya with the pen Dose counter.



- 3.2. Push Mallya fully onto the pen, pressing the button with the palm of your hand. It must be inserted all the way onto the dose selector.

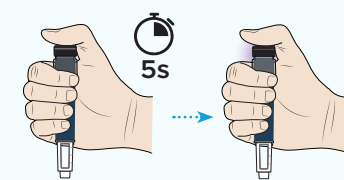


- 3.3. Make sure Mallya is properly mounted on the pen as shown on the picture.

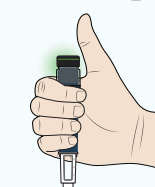


4 Activate Mallya on the new pen

- 4.1. Press firmly on Mallya button for 5 seconds, until its light turns **purple**.



- 4.2. Lift your finger, Mallya light turns **green**, indicating that Mallya is ready to be used.

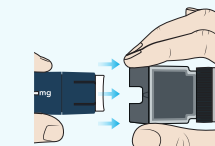


NOTE: If Mallya light does not turn **green**, make sure Mallya is sufficiently inserted on your pen. Repeat step 3.2 to push Mallya onto your pen to fully insert it. Then proceed to activate it, following the instructions in step 4.1.

Mallya is now ready for use on your new pen.
Follow the instructions in the section «Using Mallya».

1 Remove Mallya from the pen

- 1.1. Hold Mallya by the body.
- 1.2. Pull Mallya straight off the pen.
- 1.3. Pull Mallya down upright on a flat surface, with the button up.

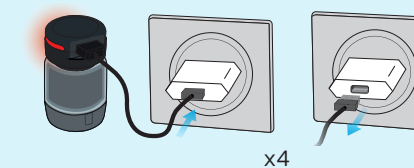


2 Reset Mallya

- 2.1. Connect Mallya to the supplied USB cable.



- 2.2. Plug-in the USB cable in a powered USB wall charger and quickly unplug it from the charger.
Repeat the plug-in/unplug process until Mallya light flashes several times and then turns off (it may require at least 4 times).



- 2.3. Disconnect Mallya from the USB cable.
- 2.4. Put Mallya down upright on a flat surface for 30 seconds, with the button up.

Mallya is now reset.

3 Restart Mallya

After reset, Mallya is powered off and must be started again. Please refer to the section «Getting started» to restart your Mallya device.

IMPORTANT: You must follow all the steps of the «Getting started» section to restart your Mallya device.

Light signals and meaning

<p>Blue Solid</p> <p>Mallya is ready to be paired.</p> <p>Before Mallya has been paired, the light is blue, regardless of the operation. No data is recorded.</p>	<p>Purple Solid</p> <p>Mallya is being activated or deactivated.</p>	<p>Green Solid</p> <p>Mallya is, either:</p> <ul style="list-style-type: none"> paired. setting a dose. injecting a dose. 	<p>Green Slow Flashing</p> <p>Mallya is charging and paired.</p>	<p>Green Rapid Flashing</p> <p>Mallya is seeing the end of an injection.</p>	<p>Orange Solid</p> <p>Mallya's battery is low. Plug-in and charge your Mallya (2h for a full charge). Mallya light is orange during injections if the battery is low.</p>	<p>Orange Rapid Flashing</p> <p>The pen dose counter must be set at 0. When the pen dose pointer is aligned with the number 0, press the dose button for 2 seconds until Mallya light turns green.</p>	<p>Red Solid</p> <p>Mallya is in error state. In this state, Mallya is not ready to record injections. Reset your Mallya and restart it. Refer to section «Resetting Mallya». If the problem persists, contact the Support service.</p> <p>The red signal is not an alarm according to IEC 60601-1-8.</p>	<p>No signal</p> <p>The light automatically turns off after a period of inactivity (10 seconds). Press lightly on the Mallya button to activate it and check its status by the light color. If the light does not turn on, press the button for 5 seconds, Mallya may be deactivated. If the light still does not turn on, despite a long and firm press on the button, the battery might be empty. Charge your Mallya.</p>
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Cleaning

Mallya is not sterile and can be reused for a single patient only.

- Mallya can be cleaned if necessary:
- If Mallya is plugged to a USB cable, unplug it.
 - Wipe the external surfaces with a soft lint-free cloth, slightly dampened with a small amount of neutral detergent if needed.
 - Dry the surfaces with a soft cloth.

Safe use information

In case of side effects or incident, please contact the manufacturer and the competent Health Authority.

Improper operation may result in serious injury or death

- If you are not certain that you injected your medication, do not start, or repeat your injection. Monitor your treatment as instructed by your healthcare provider.
- Do not leave Mallya or its accessories within the reach of children (injury, choking and strangulation hazard). Do not attach or tighten cable to or around the head or neck.
- Do not expose the device to a temperature above 40°C (104°F) or flames. If Mallya is used at high temperatures exceeding our recommendations, the surface of the device may reach a maximum temperature of 43°C. In this case, the duration of use should be limited to 10 minutes to avoid any risk of burning.
- Mallya contains a magnet. To guarantee optimal results, avoid contact with metallic parts during use, and avoid using Mallya near PACEMAKERS, DEFIBRILLATORS and BODY WORN INFUSION PUMPS or MAGNETIC RESONANCE IMAGING (MRI) ENVIRONMENT.
- Do not operate the device in a hazardous environment: presenting a risk of explosion, or containing volatile solvents (alcohol, etc.) or flammable substances (anesthetics, oxygen-rich environment, etc.).
- Mallya can only be used by patients already familiar with the pen injectors. Contact your healthcare provider, or a BIOCORP PRODUCTION authorized dealer to check your usual pen compatibility.

Improper use may result in bodily injury or property damage

- Do not expose the device to moisture. Do not immerse the device in liquids.
- Leave the device in a room at room temperature for 30 minutes before unpacking it to avoid possible malfunctions due to condensation.
- Do not disassemble, modify, or repair the device by yourself: it may cause fire, electrical shock, bodily injury, or device malfunction. Your device's warranty will be void. Periodic maintenance of Mallya is not required.
- If there is any abnormal smell, sound, heat, or smoke when using the device, stop using Mallya.
- If the device experiences an external mechanical impact (knocking, bumping, dropping, etc.) or excessive stress (inappropriate storage/transport/use conditions), this may cause malfunctioning of the device. In case of malfunctioning, do not use the device and continue your injection pen treatment. Please contact the BIOCORP PRODUCTION authorized dealer as identified on the outside of the packaging for technical support.
- In case of visible damage, do not use Mallya and contact BIOCORP PRODUCTION or its authorized dealer for technical support.
- Do not leave your Mallya and its accessories next to animals/insects or dust/plush. After use, your device must be put away in its packaging.
- Only use your Mallya with Novo Nordisk FlexPro® pen injector. Never use Mallya with any other pen.
- This device is not recommended for use by the blind or visually impaired without the help of someone trained to use the device.
- During handling operations, protect the needle with the pen cap, if it is assembled on the pen.
- Separate collection for waste electric and electronic equipment (WEEE) is required.

Wireless communication safety issues

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Mallya device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Electrical medical devices and systems are subject to special measures concerning electromagnetic compatibility (EMC) and must be installed in accordance with the EMC instructions contained in the technical note available online at <https://my-mallya.com/>.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Protect your personal healthcare data with a password on your smartphone.
- Protect your smartphone by installing antivirus software.
- Never install a mobile application from unofficial stores on your phone.
- Contact Biocorp Production for list of approved compatible apps & verified phones to be used with Mallya.
- In case of Bluetooth transmission disturbance or loss, the Mallya device will continue to track and record the history of all your injections. More information is available on the technical note available online at <https://my-mallya.com/>

- In case of use in a noisy environment (in terms of electromagnetic signal near 2.4Ghz), the Bluetooth communication is no more possible, and the connection is closed. However, the device continues to track injection. Where perturbing electromagnetic signals disappear, communication is possible.
- The Cybersecurity nomenclature corresponding to the embedded software version is available on request. Please contact a BIOCORP PRODUCTION authorized dealer if you wish to consult it.
- You are responsible for properly securing and managing your phone. If you suspect an adverse cybersecurity event related to the Mallya device or related App, contact Customer Service.
- Make sure that your phone and Mallya device are kept in a safe place, under your control. This is important to help prevent anyone from accessing or tampering with the System.
- The App used with Mallya device is not intended for use on a phone that has been altered or customized to remove, replace or circumvent the manufacturer's approved configuration or use restriction, or that otherwise violates the manufacturer's warranty.
- On rare occasions, you may get inaccurate dose readings. If the problem continues, contact Customer Service.
- The App used with Mallya device requires that your phone has the correct date and time for recording your health information. Your phone's date and time should be set to update automatically. You can check this in your phone settings.
- When using the App used with Mallya device, you should keep your phone well charged.
- Keep your phone well charged and turned on.
- Disable your phone's automatic operating system updates. After an operating system update, open your App and check your device settings to make sure it's working properly.
- Before disposing of Mallya: reset the device to delete all your personal health data.

Technical specifications

Intended Patients	Patients using a growth hormone treatment with a pen injector									
Intended Users	Users aged from 13 to 80 years old									
Intended Environment	Home use									
Accuracy of recorded doses	99% ±1 increment on test bench									
Charge and autonomy	USB AC adaptor (not provided): IEC/UL 60950-1 or IEC/UL 62368-1 certified with CE or UL marking, external module with automatic adaptation of the voltage, 90-264V input voltage range.									
Electrical consumption	5V DC, > 500mA									
Battery	Li-Ion 3.6V 25mAh									
Storage of recorded doses	The last 100 recorded increments are stored in the device's internal memory (including flow checks)									
Communication	Bluetooth Low Energy v4.2 operating in the frequency band of 2400 MHz to 2483.5 MHz. 40 channels, 2MHz spacing channel, 1 MHz channel bandwidth, 4dBm (2.5119 mW) max transmission power, -5.5dBm max EIRP (Equivalent Isotropic Radiated Power).									
Model	EFA2									
Software version	Firmware 1.0.x									
Dimensions	40.1 mm (h) x Ø 25.8 mm									
Weight	11 g									
Transport conditions	<table border="1"> <tr> <td>Temperature</td> <td>Humidity</td> <td>Pressure</td> </tr> <tr> <td>-10°C</td> <td>10%</td> <td>500hPa</td> </tr> <tr> <td>60°C</td> <td>90%</td> <td>1060hPa</td> </tr> </table> <p>The device must always be transported in its original packaging designed to protect it from damage. Keep all original packaging for future use (in case of return / transport of the device).</p>	Temperature	Humidity	Pressure	-10°C	10%	500hPa	60°C	90%	1060hPa
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Temperature	Humidity	Pressure								
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40°C	90%	1060hPa								
Operating conditions	<table border="1"> <tr> <td>Temperature</td> <td>Humidity</td> <td>Pressure</td> </tr> <tr> <td>2°C</td> <td>15%</td> <td>700hPa</td> </tr> <tr> <td>35°C</td> <td>90%</td> <td>1060hPa</td> </tr> </table>	Temperature	Humidity	Pressure	2°C	15%	700hPa	35°C	90%	1060hPa
Temperature	Humidity	Pressure								
2°C	15%	700hPa								
35°C	90%	1060hPa								
Lifetime	2 years									

Further information is included in the Technical Note, available online at my-mallya.com.

Symbols and information on the device and/or its packaging and labels

SYMBOL	DESCRIPTION
	Refer to the instruction manual / booklet. Follow instructions for use
	User manual / Operating instructions
	Manufacturer
	Serial Number
	Country and date of manufacture
	Batch number
	Unique Device Identification
# icon"/>	Model number
	Distributor
	Product reference
	Use by date
	Medical Device
	Type BF applied part (according to IEC 60601-1 continuous mode)
	Ingress Protection index IP22 (IEC 60529)
	Direct current
	Keep away from humidity
	Do not use if the packaging is damaged or opened
	WEEE: waste electrical and electronic equipment
	European Conformity Marking
	United Kingdom Conformity Assessment
	United Kingdom authorized representative
	Single patient multiple use

Radio-communication statement

The undersigned BIOCORP PRODUCTION declares that the radio equipment of the Mallya type complies with Directive 2014/53/EU. The full text of the EU Declaration of Conformity is available at the following internet address <https://my-mallya.com/>.

General information and contact information

BIOCORP PRODUCTION
ZI LAVAUUR LA BECHADE
63500 ISSOIRE
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Tel : +33 4 73 55 70 50
www.biocorp.fr

UK REP International Associates Limited
Centrum House, 38 Queen Street,
Glasgow,
Lanarkshire, G1 3DX, UK
UKRP@ia-uk.com

DISTRIBUTORS
(Authorized dealers):
Distributor details are available on the back of the Mallya box.