

Premaire™ Inhaler

Caution: Investigational device limited by federal law to investigational use

DESCRIPTION

The Premaire™ Inhaler is a hand held, pocket-sized, ultrasonic nebulizer using prefilled dosators (Premaire dosators) to deliver certain medications via inhalation.

The Premaire Inhaler consists of the following.

- Premaire Inhaler (FCC Identifier P7XMSIND)
- Battery recharger
- Safety cover for the activation button (to be used during cleaning)
- Dosator cartridge with mouthpiece
- This patient guide

INDICATIONS

The Premaire inhaler is intended for use only with Premaire dosators. Please refer to the Premaire dosator package insert for the specific indications for use.

CONTRAINDICATIONS

Please refer to the Premaire dosator package insert for specific contraindications.

WARNINGS

Warning: Low Battery

- 3 second continuous tone AFTER atomization
- FOLLOWED by a red LED next to the  icon for 8 seconds.
- The warning means that there are 5 or less actuations of the inhaler left on this battery charge.

Warning: Motor Malfunction

- 3 second continuous tone after activation.
- FOLLOWED by a red LED next to the  icon for 8 seconds.

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- This warning means that the vial is empty in which the remaining drug should be checked or there is a malfunction of the device in which the device help dept. should be called for inquiries/trouble shooting.

Warning: Inhaler Expiration

- 3 second continuous tone AFTER atomization.
- FOLLOWED by a yellow LED next to the  icon for 30 seconds.
- This warning means that there are approximately 100 actuations left for the inhaler. A new inhaler should be ordered.

Warning: Inhaler recharging

- The inhaler recharging  icon LED will be red at a low battery condition.
- The  icon LED will be FLASHING green during recharging
- The  icon LED will be SOLID green when inhaler is fully recharged.
- Inhaler CAN NOT be used while recharging.

Warning: Overheat protection

- 3 second continuous tone immediately after activating of the button.
- Under this condition the normal function of the device is not available.
- FOLLOWED by the two upper red LED's  and  alternately flashing for 8 s
- Allow 10 minutes for cooling down of the device

PRECAUTIONS

Precaution: The optimum operating temperatures for the Premaire inhaler are between 59° F (15° C) and 86° F (30° C).

Precaution: The inhaler may not deliver a dose of medication below 40° F (15° C).

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Precaution: The atomizing horn may be hot after activating the inhaler. DO NOT TOUCH.

Precaution: Do not immerse the inhaler in water.

Precaution: The inhaler may be used for up to 5 to 15 sequential actuations depending on the frequency of time between the activation after which it is necessary to wait for 10 minutes to allow the temperature safety control to reset. The overheating condition is indicated by a 3s beep followed by alternating flashing of the two (upper) red LED's for 8s just after activation of the pushbutton. Under overheating condition no function is provided.

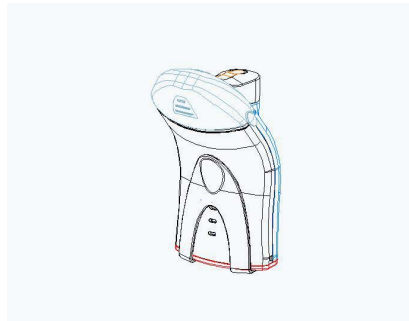
HANDLING AND USE

Setting up the inhaler (Please refer to figures below for component description)

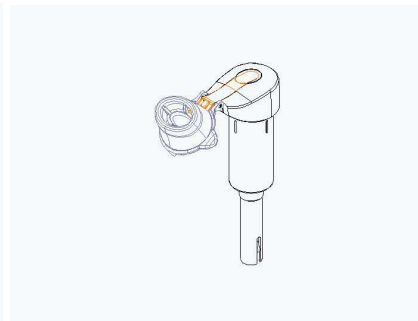
1. Carefully unpack the patient kit that contains the following items.
 - a. Premaire Inhaler
 - b. Recharger (not shown)
 - c. Safety cover for the activation button (to be used during cleaning) shown on Premaire Inhaler.
 - d. Dosator cartridge with mouthpiece



a.



c.



d.

2. Remove the atomizing horn cover from the inhaler.

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3. Place safety cover, c., over button to prevent activation while cleaning
4. Carefully rinse the atomizing area with tap water; allow time to air dry.
5. Plug the recharger into a wall outlet. Then plug recharger cable into Premaire (Charger can be used with input voltage from 90 - 264 VAC, 50/60 Hz).
6. Allow the Premaire inhaler to charge for a minimum of 8 hours before its first use.
7. The  icon LED will be flashing green while recharging and change to solid green when fully charged.

Delivery of a dose

8. Remove the dosator cartridge, d., from its container.
9. Turn the dosator cartridge upside down so the top is resting on a flat, stable surface such as a counter or tabletop with the mouthpiece positioned over the spout.
10. Grasp the plastic cylinder housing and press down until a click is heard and a small drop of solution appears at the end of the spout. The dosator cartridge is now activated. Repeat this step if you do not hear the click.
11. Insert the activated dosator cartridge into the inhaler's reservoir. Gently pull back the mouthpiece to expose the spout.

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12. The Premaire system must be primed before its first use. To prime, press activation button “2” times (pausing 2 seconds between each depression) until a mist appears.
13. Wipe the atomizer horn with a clean cloth. Gently lower the mouthpiece to cover the spout and the atomizing horn on the inhaler. The mouthpiece will engage the inhaler with a click. The hinged mouthpiece on the dosator cartridge must align with the atomizing horn on the device.



14. The inhaler is ready to deliver medication.
15. Exhale fully.
16. Place the mouthpiece in your mouth, ensuring you completely seal the mouthpiece with your lips.

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17. Press the activation button on the inhaler until you hear the motor, then release the button and start inhaling through the mouthpiece. It is important to breath normally and not too quickly or deeply. Once the sound from the motor is complete, you should stop inhaling. You should hold your breath for 10 seconds.
18. You have received one “puff” of medications. If you are directed to take two “puffs” to receive a complete dose, wait 1 minute then repeat steps 14-16.

Recharging the device

19. The inhaler must be fully recharged after the red LED  uminates.
20. Plug the recharger into a wall outlet then plug recharger cable into Premaire
 - a. The inhaler recharging  icon LED will be red at a low battery condition.
 - b. The  icon LED will be FLASHING green during recharging at an interval of 1/2 second on and 1/2 seconds off.
 - c. The  icon LED will be SOLID green when the inhaler is fully recharged.
 - d. Inhaler CAN NOT be used while recharging, however the inhaler can deliver 3 actuations within 2 minutes of recharging.
 - e. If battery pack overheats while charging, the green LED will have a rapid flash rate of 1/6 second on and 1/6 second off. Discontinue charging to allow battery pack fault to reset.
21. The inhaler will fully charge in approximately 5 hours.

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SPECIFICATIONS

Electrical requirements: 90 - 264 VAC, 50/60 Hz

Operating Temperature Range: 59° F – 86° F (15° C - 30° C)

Lag time between start of motor and atomizing: < 1 second

Atomizing time: ≈ 2.1 second

FCC

This inhaler generates and uses radio frequency energy and if not installed and used properly, that is, in strict accordance with the manufacturer's instructions, may cause interference to radio and television reception. It has been certified by the FCC to comply with the limits for consumer ISM equipment in accordance with the specifications in Subpart C of Part 18 of FCC Rules, which are designed to provide reasonable protection against such interference in a residential installation. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following methods:

- Reorient the receiving antenna
- Relocate the **Premaire™** with respect to the receiver
- Move the **Premaire™** away from the receiver

The user may find the following booklet prepared by the Federal Communications Commission helpful:

"How to Identify and Resolve Radio-TV Interference Problems"

This booklet is available from the U.S. Government Printing Office. Washington, DC 20402, Stock No. 004-000-00345-4.

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