Flexichamber®

Single patient, multi-use, disposable

℞ only

Anti-static Valved Collapsible Holding Chamber

Instructions for use: Before using Flexichamber®, it is important to read and understand these instructions and the instructions provided with your Metered Dose Inhaler (MDI).

Introduction

Flexichamber® is a compact, anti-static valved collapsible holding chamber used to deliver medication from most pressurized Metered Dose Inhalers (pMDIs). This device is designed to be used for delivering aerosol medication into the lungs.

When you release a spray of aerosol from the MDI into the device, the medication is held in the reservoir bag for a moment. The reservoir bag removes most larger aerosol drug particles while allowing smaller particles to enter into the lungs during inhalation.

The Flexichamber® reservoir bag pulls inward during inhalation enabling the patient to appreciate the depth of inhalation of the medication. The compact design of the device makes it convenient to carry. The removable Backpiece allows the device to be easily cleaned.

Please discuss the use of Flexichamber® with your physician, pharmacist, respiratory therapist, or other healthcare professional. Always read and follow instructions as provided in this product leaflet and as directed by your healthcare professional.

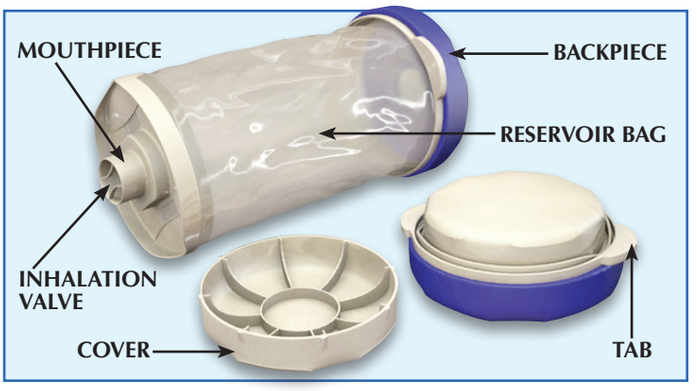
Indications For Use

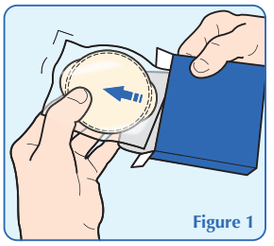
Flexichamber® is an anti-static valved collapsible holding chamber intended to be used by patients under the care or treatment of a physician or licensed healthcare professional. The device is intended to be used by these patients to administer aerosolized medication from most pressurized Metered Dose Inhalers (pMDIs). The intended environments for use include home, hospitals, and clinics. This product is intended for patients who can follow verbal instructions.

Instructions For Use

1. Remove device from carton and outer plastic wrap covering the device *(See Figure 1)*.
2. Before using the product, carefully examine the device for any damage (such as loose, broken, or missing parts; or holes, tears, or rips in the Reservoir Bag or Backpiece). Check for and remove any foreign objects in the chamber (Reservoir Bag) and mouthpiece to prevent possible choking hazards. This product contains a duckbill-shaped inhalation valve which is a small part and could pose a choking hazard if removed. Do not remove the inhalation valve. Proper disassembly and cleaning instructions are provided with this leaflet. If the product is damaged or is missing any parts then it should be replaced immediately. If necessary, use the MDI alone until a replacement Flexichamber® is obtained. If the patient's symptoms worsen, please seek immediate medical care.
3. To prepare the device for use, remove the Cover from the device *(See Figure 2)*. With the Mouthpiece facing you, place thumbs on the Tabs, and push the Backpiece up toward you *(See Figure 3)*.
4. Once the Mouthpiece has popped out of the base, gently pull it away from the Backpiece to expand the Reservoir Bag *(See Figure 4)*.
5. Remove the cap from the MDI *(See Figure 5)*.
6. Shake the MDI immediately before each use as described in the instructions provided with the MDI medication *(See Figure 6)*.
7. Insert the MDI into the Backpiece of the device *(See Figure 7)*. Ensure the MDI is securely inserted into the Backpiece.
8. Grasp the Backpiece firmly, place Mouthpiece into mouth and close lips around Mouthpiece to form an effective seal. Press down on the MDI to dispense one dose of medication into the Reservoir Bag. Administer only one (1) puff at a time *(See Figure 8)*.
9. Inhale slowly and deeply through the mouth until a full breath has been taken. The Reservoir Bag may pull inward slightly as you inhale *(See Figure 9)*. If possible, hold breath for 5-10 seconds, while keeping lips tightly around the Mouthpiece to maintain seal for 2-3 breaths.
10. Repeat steps 8-9, following the instructions provided with the MDI and as directed by your physician, including amount of time to wait between doses.
11. ***Important Note:*** Before repeating steps 8-9 ensure the Reservoir Bag has been restored to its full size (no longer in a deflated or collapsed state) by pulling the Mouthpiece gently away from the Backpiece *(See Figure 4)*.

(Continued on reverse side)

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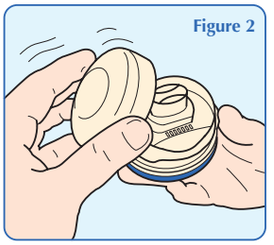
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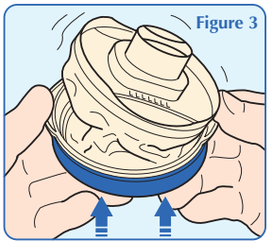
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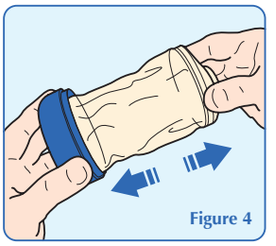
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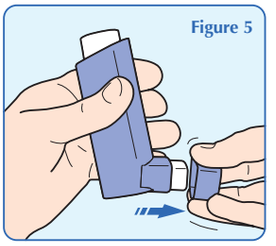
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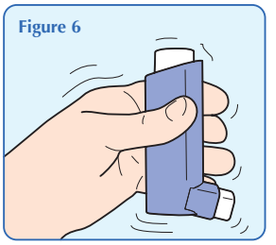
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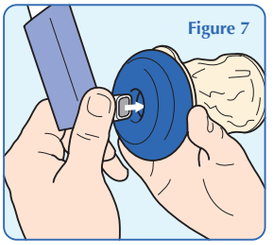
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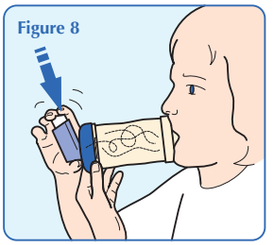
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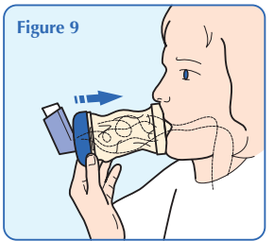


Figure 9

When finished taking your medication as prescribed by your physician, remove the MDI from the Backpiece and close the device by carefully twisting the Mouthpiece and pushing toward the Backpiece, not allowing the Reservoir Bag to become lodged between the Backpiece and the Mouthpiece *(See Figure 10)*. Replace the Cover.

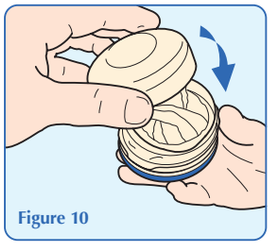


Figure 10

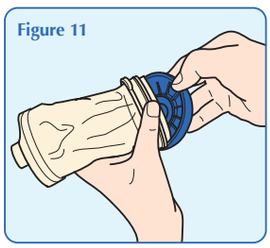
Helpful Hints

1. Take slow deep breaths during inhalations.
2. For small children and elderly who may have difficulty using Flexichamber®, allow another adult to assist with administration.
3. Keep Flexichamber® closed and with Cover in place when not in use.

Important Cleaning Instructions

Clean Flexichamber® by hand weekly, or more frequently, if required depending on your use of the product. **Flexichamber® is NOT dishwasher or microwave safe.**

1. Remove the Cover.
2. With the Mouthpiece facing you, place thumbs on the Tabs, and push the Backpiece up toward you to open the device.
3. Remove the Backpiece from the device. **Do not remove any other parts during disassembly and cleaning as it may result in damage to the device and present a possible choking hazard** *(See Figure 11)*.
4. Wash the parts in lukewarm water using a mild, liquid dish detergent and a soft cloth. Do not use abrasive detergents or cloths, or any cleaning agents other than mild dish detergent, as this may result in tears, holes, or other damage to the Reservoir Bag *(See Figure 12)*.
5. Use fresh, lukewarm water to rinse the device and its parts.
6. To dry, gently shake off excess water. **Let all parts air dry completely, keeping the device in its open, extended position** *(See Figure 13)*. Do not place near artificial heat, such as a dishwasher or oven.
7. When parts are completely dry, reassemble the Backpiece firmly into place. Visually inspect to ensure the Backpiece is on tightly and no other parts are loose, missing, or damaged. Check for and remove any foreign objects or materials.
8. Replace the Cover and close the device by carefully twisting and pushing down toward the Backpiece *(See Figure 14)*.
9. Store in a cool, dry place.
10. This is a multi-use device, but should be examined prior to each use for signs of damage. Check for loose, broken, or missing parts; or holes, tears or rips in the Reservoir Bag or Backpiece. Damaged devices should be replaced immediately.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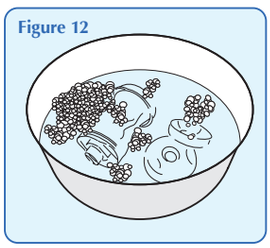
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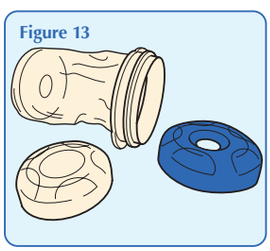
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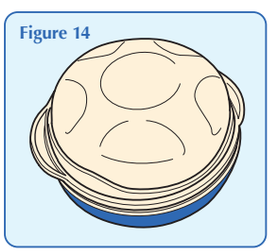
Figure 14

Important Information Concerning Your Medication

1. Package insert dosing instructions should be consulted for all metered-dose inhalers (MDIs) when used with Flexichamber®. Dosage and administration recommendations vary for different MDIs. The limitations and conditions of use for each product should be considered before utilizing this device.
2. Product may need to be replaced after repeated use. Proper storage, cleaning, and environmental conditions will affect the product life span.
3. Store in a cool, dry place.
4. Do not share this device with anyone. It is intended for use with a single patient.
5. Do not place in dishwasher. Wash Flexichamber® by hand using lukewarm water and a mild, non-abrasive dish detergent.
6. If you notice medication build-up within the Reservoir Bag, wash as described in the Important Cleaning Instructions section of this product insert.
7. This product contains small parts (duckbill-shaped inhalation valve) which could pose a possible choking hazard if removed and ingested. **Never remove the inhalation valve. Do not remove any other parts, except as described in the cleaning instructions.**
8. Prior to each use, check the device for and remove any foreign objects or materials. Check for any damage to the product. Do not use if damaged.

Do not leave device unattended with children.

Note: You will need a physician's prescription for a new Flexichamber® device.

Caution: Federal law restricts this device to sale by, or on the order of, a physician.

HOW SUPPLIED:

Flexichamber® Anti-static Valved Collapsible Holding Chamber — NDC 23594-901-01

cerecor

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Rev 01/18 FC01172018PIv1
Patent flexichamber.com
1116 FLX DEV IFU WEB ENG

Flexichamber® Face Mask Rx only

For Use With The Flexichamber®
Anti-static Valved Collapsible Holding Chamber

Single patient, multi-use, disposable

Background

Before using the Flexichamber® Face Mask with the Flexichamber® Anti-static Valved Collapsible Holding Chamber, it is important to read and understand these instructions, the instructions provided with the Flexichamber® Anti-static Valved Collapsible Holding Chamber, and the instructions provided with your Metered Dose Inhaler (MDI). Use as directed by your healthcare professional.

Indications For Use

The Flexichamber® Face Mask is intended to be used with the Flexichamber® Anti-static Valved Collapsible Holding Chamber and by patients under the care or treatment of a physician or licensed healthcare professional. The Flexichamber® Face Mask and the Flexichamber® Anti-static Valved Collapsible Holding Chamber are intended to be used by these patients to administer aerosolized medication from most pressurized Metered Dose Inhalers. The intended environments for use include home, hospitals, and clinics. This product is intended for patients who can follow verbal instructions.

Introduction

For most children, the MDI delivers medicine most effectively when given through a valved holding chamber. A valved holding chamber contains a one-way valve that does not allow the patient to breathe back into the chamber. This feature is very important because it allows young children to breathe normally and still get a reliable dose of medication. The mask that is attached to the chamber fits over the child's nose and mouth and forms a seal. This seal keeps the medication from leaking out into the air.

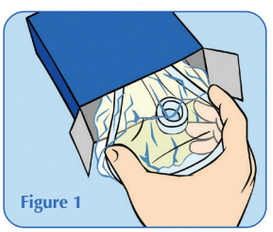
Figure 1

Instructions For Use

1. Remove the Flexichamber® Face Mask from the carton and outer plastic wrap covering the mask. *(See Figure 1).*
2. Attach the Flexichamber® Face Mask to the end of the Flexichamber® Anti-static Valved Collapsible Holding Chamber *(See Figure 2).*

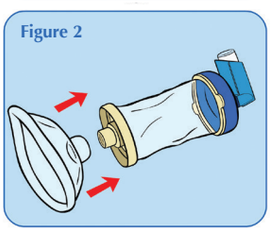
Figure 2

3. Apply the mask over the mouth and nose and ensure there is a good seal *(See Figure 3).*

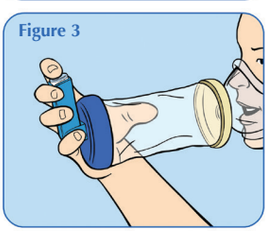
Figure 3

4. Press down on the MDI to dispense one dose of medication into the Reservoir Bag. Administer only one (1) puff at a time *(See Figure 4).*

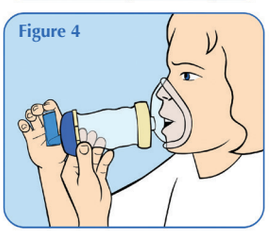
Figure 4

5. Inhale slowly and deeply through the nose and mouth until a full breath has been taken. The Reservoir Bag may pull inward slightly as you inhale *(See Figure 5).* If possible, hold breath for 5-10 seconds, while maintaining a seal with the mask.
6. Repeat steps 4-5, following the instructions provided with the MDI, the Flexichamber® Anti-static Valved Holding Chamber, and as directed by your physician, including amount of time to wait between doses.

7. ***Important Note:*** Before repeating steps 4-5 ensure the Reservoir Bag has been restored to its full size (no longer in a deflated or collapsed state) by pulling the Mouthpiece gently away from the Backpiece *(See Figure 6).*

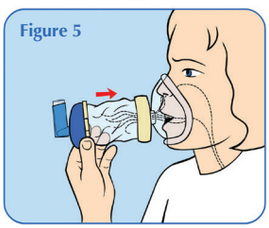
Figure 5

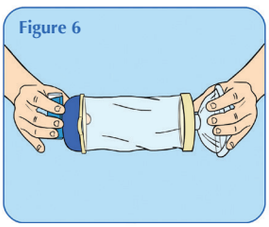
Figure 6

When finished taking your medication as prescribed by your physician, remove the MDI from the Backpiece; remove the face mask, and then close the device by carefully twisting the Mouthpiece and pushing toward the Backpiece, not allowing the Reservoir Bag to become lodged between the Backpiece and the Mouthpiece *(See Figure 7).* Replace the Cover.

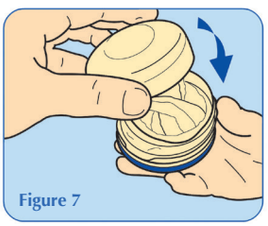
Figure 7

Important Cleaning Instructions

Clean the Flexichamber® Face Mask by hand weekly, or as required depending on your use of the product. **The mask is NOT dishwasher or microwave safe.**

1. Remove the mask from the Flexichamber® device.
2. Wash in lukewarm water using a mild, liquid dish detergent and a soft cloth. Do not use abrasive detergents or cloths as this may result in damage to the face mask *(See Figure 8).*

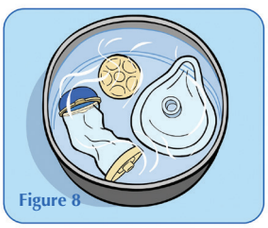
Figure 8

3. Use fresh lukewarm water to rinse the mask.
4. To dry, gently shake off excess water. Let the mask air dry. Do not place near artificial heat, such as a dishwasher or oven.
5. When completely dry, store the Flexichamber® Face Mask with the Flexichamber® Anti-static Valved Collapsible Holding Chamber.
6. Store in a cool, dry place.

Caution: Federal law restricts this device to sale by, or on the order of, a physician.

HOW SUPPLIED:

The Flexichamber® Face Mask comes in three (3) sizes:

Small Child Mask	NDC # 23594-903-01
Large Child Mask	NDC # 23594-903-02
Small Adult Mask	NDC # 23594-903-03

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