

# Instructions For Use

## Dry powder inhaler (MRX003-T10 DPI)

**REF** MRX003-R, MRX003-Y, MRX003-B

Read these Instructions for Use before you start to use the dry powder inhaler (DPI) and each time you replace your inhaler. There may be new information.

### Intended Purpose:

The Dry Powder Inhaler (DPI) device (MRX003-T10 DPI) is a mechanical, hand-held, multi-use, breath-actuated, capsule-based inhalation device for pulmonary dosing and administration of dry powder medicinal products.

The DPI is used in conjunction with dry-powder capsules containing medicinal products used for management of pulmonary disease.

### Patient Target Group

The device is intended patient self-administration of therapy or administration to the patient by a caregiver and/or healthcare professional. The device is intended to be used by adults (i.e., aged 18 years or older) with symptoms of COPD.

### Clinical benefit:

The DPI enables inhalation of the medicine contained in the capsules prescribed by a healthcare professional. The device is intended to deliver a maintenance bronchodilator treatment to relieve symptoms of COPD patients; *the product is not intended to be used in the initial treatment of acute episodes of bronchospasm, i.e. rescue therapy.*

### Performance Characteristics:

The DPI, which you should put the dry-powder capsule into, makes holes in the capsule and allows for inhalation of the powder. One device is used once per day with one capsule to administer the medicinal product.

### Precautions:

- **Do not** use your dry product inhaler to take any other medicine than dry powder capsules ("capsules").
- **Do not** use the dry powder inhaler beyond the device expiry date.
- **Do not** use the dry powder inhaler for more than 6 months (180 actuations)

### Becoming familiar with your dry powder inhaler:

If this is your first time using an inhaler of any kind, make sure you have had sufficient training from your physician before you use the dry powder inhaler.

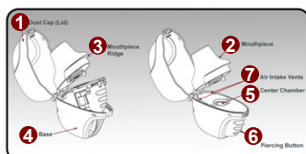


Figure A

**The parts of your dry powder inhaler include:** (See Figure A)

1. dust cap (lid),
2. mouthpiece,
3. mouthpiece ridge,
4. base,
5. centre chamber,
6. piercing button,
7. air intake vents

### Taking your full daily dose of medicine requires 4 main steps:

#### Step 1. Opening your dry powder inhaler:

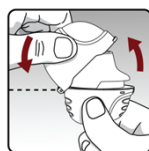


Figure B

After removing your dry powder inhaler from the pouch:

- Open the dust cap (lid) by lifting the front ridge.
- Pull the dust cap (lid) upwards away from the base to expose the mouthpiece. (See Figure B).

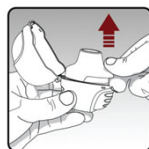


Figure C

- Open the mouthpiece by pulling the mouthpiece ridge up and away from the base so the centre chamber is showing. (See Figure C)

#### Step 2. Inserting the capsule into your dry powder inhaler:



Figure D

Remove a capsule from the blister (only immediately before use, see blister handling) and place the capsule in the centre chamber of your dry powder inhaler. It does not matter which side of the capsule is up or down. (See Figure D)

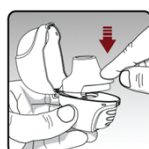


Figure E

Close the mouthpiece firmly against the gray base until you hear a click. Leave the dust cap (lid) open. (See Figure E)

#### Step 3. Piercing the capsule:



Figure F

- Hold your dry powder inhaler with the mouthpiece pointed up. (See Figure F)
- Press the piercing button once fully in until it stops, then release. This is how you make holes in the capsule and allows the medication to be released when you breathe in.
- **Do not** press the piercing button more than one time.
- **Do not** push upward on the base while pressing the piercing button. This may cause the device to open, such as for cleaning (see Figure J).
- **Keep** your inhaler in an upright position
- **Do not** shake your dry powder inhaler.

#### Step 4. Taking your full daily dose (2 inhalations from the same capsule):



Figure G

**Breathe out completely in 1 breath,** emptying your lungs of any air. (See Figure H)

**Important: Do not breathe into your dry powder inhaler.**

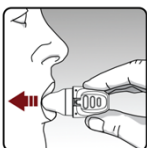


Figure H

With your next breath, take your medicine:

- **Hold your head in an upright position while you are looking straight ahead.** (See Figure H)

- Raise your dry powder inhaler to your mouth in a horizontal position. Do not block the air intake vents.
- Close your lips tightly around the mouthpiece.
- Breathe in slowly and deeply until your lungs are full. You should hear and/or feel the capsule vibrate (rattle). (See Figure H)
- Hold your breath for a few seconds and, at the same time, take your dry powder inhaler out of your mouth.
- Breathe normally again. Resume normal breathing. Repeat step 4 once, in order to empty the capsule completely.

**Important: Do not press the piercing button again.**

#### Caring for and storing your dry powder inhaler:

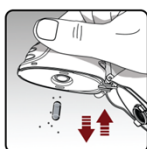


Figure I

After taking your daily dose, open the mouthpiece and tip out the used capsule into your trash can.

Remove any capsule pieces or powder build up by turning your dry powder inhaler upside down and gently, but firmly, tapping it. (See Figure I). Then close the mouthpiece and dust cap for storage.



Store the dry powder inhaler at room temperature (not more than 30°C).

#### Cleaning your dry powder inhaler:

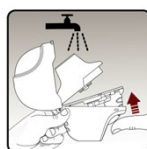


Figure J

Clean your dry powder inhaler monthly. (See Figure J)

**It takes 24 hours to air dry your dry powder inhaler after you clean it.**

- **Do not** use cleaning agents or detergents.
- **Do not** place your dry powder inhaler in the dishwasher for cleaning.

#### Cleaning Steps:

- Open the dust cap and mouthpiece.
- Open the base by pushing the piercing button upwards.
- Look in the centre chamber for capsule pieces or powder build up. If seen, tap out.
- Rinse your dry powder inhaler with warm water, pressing the button a few times so that the centre chamber and the piercing needle is under the running water. Check that any powder build up or capsule pieces are removed.
- Dry your dry powder inhaler well by tipping the excess water out on a paper towel. Air-dry afterwards, leaving the dust cap, mouthpiece, and base open by fully spreading it out so that it dries completely.
- **Do not** use a hair dryer to dry your dry powder inhaler.
- **Do not** use your dry powder inhaler when it is wet. If needed, you may clean the outside of the mouthpiece with a clean damp cloth.

#### Blister handling



Figure K

Each day, separate only 1 of the blisters from the blister card by tearing along the perforated line. (See Figure K)



Figure L

- Remove the capsule from the blister:
- Do not cut the foil or use sharp instruments to take out the capsule from the blister.
  - Bend 1 of the blister corners with an arrow and separate the aluminium foil layers.
  - Peel back the printed foil until you see the whole capsule (only immediately before use). (See Figure L)
  - If you have opened more than 1 blister to the air, the extra capsule should not be used and should be thrown away.

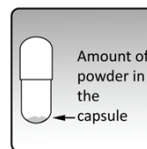


Figure M

Each capsule contains only a small amount of powder. (See Figure M) This is 1 full dose.

Do not open the capsule or it may not work.

#### Residual Risks

**Important tips to help ensure that you are properly taking your full dose of your medicine:**

- Press the piercing button 1 time; Breathe in 2 times; Breathe out completely before each of the 2 inhalations.
- To get your full medicine dose each day, you must breathe in **2 times** from the same capsule. Make sure you breathe out completely each time before you breathe in from your dry powder inhaler
- Keep your dry powder inhaler with the mouthpiece pointed up when pressing the piercing button.
- **Press piercing button 1 time** to pierce the capsule.
- **Do not** breathe out into your dry powder inhaler.
- Keep your dry powder inhaler in a horizontal position and keep your head upright, looking straight ahead, when breathing in.
- Check the centre chamber of your dry powder inhaler for capsule pieces or powder build-up. If pieces or powder are seen, tap out before use.
- Clean your dry powder inhaler monthly and dry thoroughly.

#### Warnings/Precautions

- There are no known contraindications for this device.
- There are no special precautions for device disposal.
- **Do not** use the device if it is visibly damaged or if a capsule remains in the device.
- Consult a healthcare professional in case of any abnormal reactions to device use.
- Report to the manufacturer or local health authority any issue related to the device leading to potential deterioration of health.

#### Legal Manufacturer

of the dry powder inhaler:



Phagentis SA  
Via Figino 6  
6917 Barbengo  
CH

#### Additional Symbols (not explained above):

<b>REF</b>	Catalogue Number
<b>#</b>	Model Number
<b>LOT</b>	Batch Number
<b>CE</b>	CE marking of conformity
<b>EU REP</b>	EU Authorised Representative
<b>EU</b>	EU Importer
<b>UDI</b>	Unique Device Identifier
<b>MD</b>	Device expiration date
<b>MD</b>	Medical Device



Issued: JUN2025  
Version: IFU-V10-DO