Instructions for use

for use at home

1 IMPORTANT INFORMATION

Please read these instructions for use carefully and completely. Do not discard, so you can consult them at a later date. If you fail to comply with the instructions for use, injury or damage to the device cannot be ruled out.

These instructions for use are intended for the user at home. Separate instructions for use are available for technical personnel on the Internet at www.pari.de/en/products (on the respective product page) or as a hard copy on request from PARI GmbH.

Safety-critical warnings are categorised according to hazard levels in these instructions for use:

- The signal word WARNING is used to indicate hazards which, without precautionary measures, can result in serious injury or even death.
- The signal word CAUTION is used to indicate hazards which, without precautionary measures, can result in minor to moderate injury or impair treatment.
- The signal word NOTE is used to indicate general precautionary measures which are to be observed to avoid damaging the device during use.

⚠️ WARNING

When treating babies, children and anyone who requires assistance, the following must be observed without fail:

- Babies, children and anyone who requires assistance must be supervised constantly by an adult during inhalation therapy. This is the only way to ensure safe and effective treatment. Such persons often underestimate the hazards involved, thus resulting in a risk of injury.
- The product contains small parts. Small parts can block the respiratory tract and pose a choking hazard. Therefore, make sure that you always keep this product out of the reach of babies and infants.

⚠️ CAUTION

- The VORTEX® can be disinfected up to 60 times as described in chapter 4. If you use the device every day, replace all components of your holding chamber after a year, because the material can change over time. This might impair the effectiveness of the treatment.
- Only use medications that have been prescribed by your doctor and follow your doctor’s dosing instructions as well as the instructions for use of the medication concerned. If treatment causes the patient’s health to worsen, contact a doctor immediately.
2 PRODUCT DESCRIPTION

2.1 Components

Check whether all components are included in the package according to the following description. Should anything be missing, please notify the dealer from whom you obtained the VORTEX® at once.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(1)</td>
<td>Inhalation chamber (antistatic)</td>
</tr>
<tr>
<td>(2)</td>
<td>Protective cap</td>
</tr>
<tr>
<td>(3)</td>
<td>Mouthpiece with inspiratory and expiratory valve (3a)</td>
</tr>
<tr>
<td>(4)</td>
<td>Blue connecting ring with opening for the mouthpiece of the MDI (pre-fitted to the inhalation chamber)</td>
</tr>
<tr>
<td>(5)</td>
<td>Baby or child mask (must be purchased separately; not included in the package for item no. 051G1000)</td>
</tr>
<tr>
<td>(6)</td>
<td>Adult mask soft (must be purchased separately; only included with item no. 051G1060)</td>
</tr>
<tr>
<td>(7)</td>
<td>Mask connector (only included with item no. 051G1060)</td>
</tr>
</tbody>
</table>
### 2.2 Materials used

<table>
<thead>
<tr>
<th>Material</th>
<th>Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polycarbonate</td>
<td>Inhalation chamber, mouthpiece</td>
</tr>
<tr>
<td>Aluminium</td>
<td>Inhalation chamber</td>
</tr>
<tr>
<td>Polypropylene</td>
<td>Baby mask, child mask, adult mask soft, mask connector</td>
</tr>
<tr>
<td>Polyethylene</td>
<td>Protective cap</td>
</tr>
<tr>
<td>Silicone</td>
<td>Inspiratory and expiratory valve, connecting ring</td>
</tr>
<tr>
<td>Thermoplastic elastomer</td>
<td>Baby mask, child mask, adult mask soft</td>
</tr>
</tbody>
</table>

All materials used in the VORTEX® are latex-free.

### 2.3 Intended use

The VORTEX® is a holding chamber which is used in combination with medication sprays and metered dose inhalers (MDI) to treat diseases of the respiratory tract. It includes a metal chamber and works with the cyclone twist principle to ensure reliably metered dosing. With the appropriate mask, it is also suitable for application with babies and children.

The VORTEX® is used to:
- minimise errors of coordination when using metered dose inhalers (MDI) and
- prevent delivery of excess medication to the mouth and throat, and the adverse effects associated therewith.

With its flexible connecting ring, the device can be used with all commonly used metered dose inhalers.

Use only PARI accessories to ensure that the treatment is performed properly.
3 INHALATION

3.1 Preparation

⚠️ WARNING
Since the inhalation chamber of the VORTEX® is not completely closed, small particles can get into it, and may be breathed in during inhaling (danger of choking). Therefore, make sure there are no foreign bodies in the VORTEX® before every use.

⚠️ CAUTION
Before each use, inspect the VORTEX® for damage. Replace any broken, misshapen or seriously discoloured parts. Please also follow the instructions for assembly given below. Ensure that the blue valve (3a) is positioned on the mouthpiece as shown (see Section 4.2).

Damaged components and an incorrectly assembled holding chamber can obstruct function and thus also impair treatment.

- Remove the sealing cap on the MDI.
- Shake the MDI vigorously before each use.

- Insert the mouthpiece of the MDI into the connecting ring of the VORTEX®.
- Pull the protective cap (2) off.
  - It is easier to pull the protective cap off if you twist it slightly while pulling.
- Check that the valve (3a) is seated correctly.
Using with Baby or Child mask

- Attach the Baby or Child mask (5) directly to the mouthpiece.

Using with Adult mask

- Insert the mask connector (7) in the opening on the adult mask soft (6).
- Attach the adult mask soft with the mask connector to the mouthpiece of the VORTEX®.

**CAUTION**

It is essential to ensure that the blue expiratory valve plate on the adult mask soft is pressed out before each use. If the plate has been pressed in, it is possible that insufficient medication may be delivered during the application.

3.2 Performing the inhalation

**CAUTION**

Before the patient starts inhaling, ensure that all parts are firmly connected to each other. Otherwise, it is possible that insufficient medication may be delivered.

- Hold the mouthpiece of the VORTEX® between your teeth and enclose it with your lips. Alternatively, place the VORTEX® with mask gently on the face. Mouth and nose must be covered.
• As the patient begins inhaling deeply and slowly, operate the MDI.
• Hold your breath briefly.
• Then breathe out slowly into the mouthpiece.

For babies and infants who inhale using a mask, we recommend that you operate the MDI shortly before fitting the mask on the child’s face. This will make it easier to use.

---

**CAUTION**

Children younger than 18 months should inhale four to six times; children older than 18 months should inhale deeply two to four times. Otherwise, it is possible that insufficient medication may be delivered.

---

For adults, one breath is sufficient to inhale the medication from the VORTEX®.
4 CLEANING AND DISINFECTION

Clean the VORTEX® thoroughly before using it for the first time. The VORTEX® must be cleaned regularly and immediately after the application, particularly if contamination is visible.

If the patient suffers from an infectious disease or is in a high risk group (e.g., patients with cystic fibrosis), ask your doctor or pharmacist about additional recommended hygiene procedures.

4.1 Preparation

- Remove the connecting ring and, if present, the mask together with the mask connector as necessary (do not remove the mouthpiece or the protective cap!).

4.2 Cleaning

- Thoroughly clean all components in warm, drinkable tap water and dishwashing liquid.
- Rinse all parts thoroughly under warm running water.
- If necessary, use a stream of tap water to push the valve (3a) gently back into its original position, and then shake to remove excess water.
4.3 Disinfection

Disinfect the VORTEX® and the accessories used after cleaning (the VORTEX® can only be disinfected effectively if it has been cleaned first).

In boiling water

- Place the individual parts of your VORTEX® in boiling water for at least 5 minutes. Use a clean pot and fresh drinking water.
  
  If your water is very hard, scale may be deposited on the parts as a milky coating. This can be prevented by using softened water.

NOTE

Plastic will melt if it comes into contact with the hot base of the pot. Therefore, make sure there is plenty of water in the pot. This way you will avoid damaging the components.

Using a standard thermal disinfector for baby bottles (not a microwave oven)

Disinfection must last at least 15 minutes. Regarding disinfection and the quantity of water required for this, it is essential to follow the instructions for use of the disinfector you are using. Always check carefully that it is clean and fully functional.

CAUTION

A damp environment may encourage the growth of bacteria. Therefore, remove the individual components from the pot or disinfector as soon as disinfection has finished. Dry the parts as described in chapter 4.4. The risk of infection is reduced when the parts are dried completely.

4.4 Drying and storage

- Dry the VORTEX® and the accessories used thoroughly. The antistatic properties of the VORTEX® mean that you can dry it with a clean tea towel.
- Put the protective cap back on.
  
  The protective cap prevents the mouthpiece of the VORTEX® from being damaged while it is being transported or stored.
- Insert the connecting ring in the inhalation chamber.
- Keep the VORTEX® and its accessories in a safe, dry and dust-free place.
5 MISCELLANEOUS

5.1 Disposal
The VORTEX® may be disposed of with domestic waste unless the disposal regulations in the respective country provide otherwise.

5.2 Contact
For product information of any kind, or if you have any problems or questions about handling, please contact our Service Center:
Tel.: +49 (0)8151-279 279 (German-speaking)
    +49 (0)8151-279 220 (international)

6 SPARE PARTS AND ACCESSORIES

<table>
<thead>
<tr>
<th>Description</th>
<th>Part no.</th>
</tr>
</thead>
<tbody>
<tr>
<td>VORTEX® Mouthpiece with Valve</td>
<td>051B0100</td>
</tr>
<tr>
<td>VORTEX® Connecting Ring for metered dose inhaler</td>
<td>051E5004</td>
</tr>
<tr>
<td>VORTEX® Baby Mask Ladybug, 0–2 years</td>
<td>041G0712</td>
</tr>
<tr>
<td>VORTEX® Child Mask Frog, age 2 and older</td>
<td>041G0713</td>
</tr>
<tr>
<td>VORTEX® Adult Mask soft with mask connector</td>
<td>051G0740</td>
</tr>
</tbody>
</table>

Information as of: April 2012