

Package leaflet: Information for the user

VOLUMATIC Spacer Device

Read all of this leaflet carefully before you start using your VOLUMATIC Spacer Device.

- Keep this leaflet. You may need to read it again. If you have any questions, ask your doctor or pharmacist.
- The medicine for use with this device has been prescribed for you. Don't pass it on to other people - it may harm them even if their symptoms seem to be the same as yours.
- For hygiene reasons, the VOLUMATIC Spacer Device must be used by a single patient.
- Do not allow your child to play with the VOLUMATIC Spacer Device.

For use only with GSK Inhalers as prescribed by your doctor.

In this leaflet:

1. **What VOLUMATIC Spacer Device is and what it is used for**
2. **Before you use VOLUMATIC Spacer Device**
3. **How to use VOLUMATIC Spacer Device**
4. **How to look after your VOLUMATIC Spacer Device**

1. What VOLUMATIC Spacer Device is and what it is used for

A VOLUMATIC Spacer Device is a large-volume spacer device which is intended to make it easier for you to use your Inhaler effectively. It helps the medicine reach your lungs where it is needed instead of being deposited at the back of the throat where it may be less effective or may cause irritation. It makes it easier to use your Inhaler because you don't have to press down on the Inhaler and breathe in at the same time.

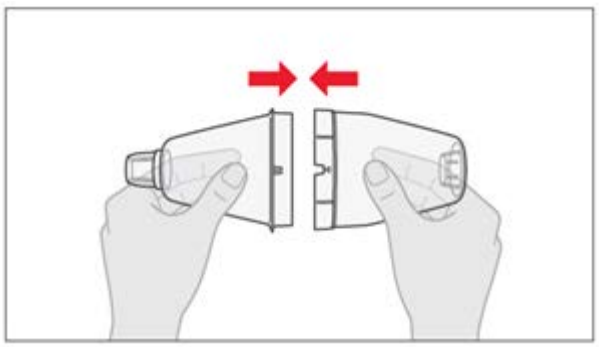
2. Before you use VOLUMATIC Spacer Device

Clean the VOLUMATIC Spacer Device before first use (see the section 4 "How to look after your VOLUMATIC Spacer Device").

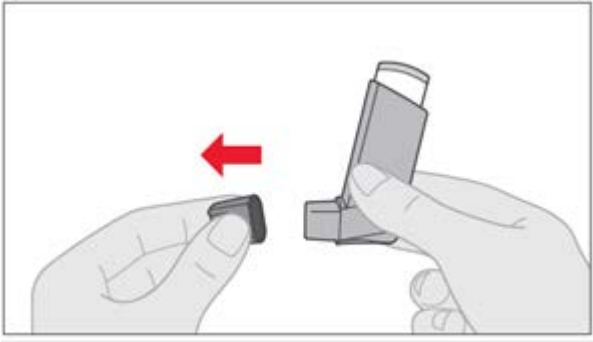
3. How to use VOLUMATIC Spacer Device

How to prepare the VOLUMATIC Spacer Device for use with your Inhaler.

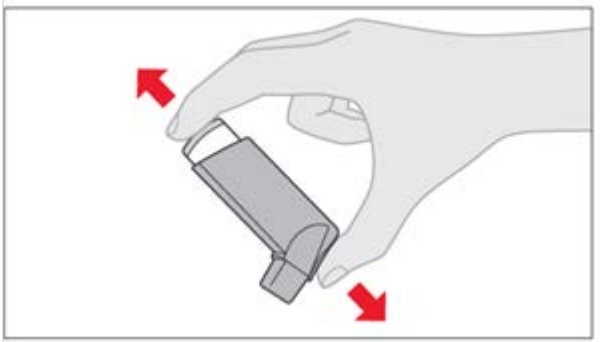
1. Fit the two halves of the VOLUMATIC Spacer Device together. Line up the notch on one half with the slot on the other (these are marked with small arrows), then press the two halves firmly together.



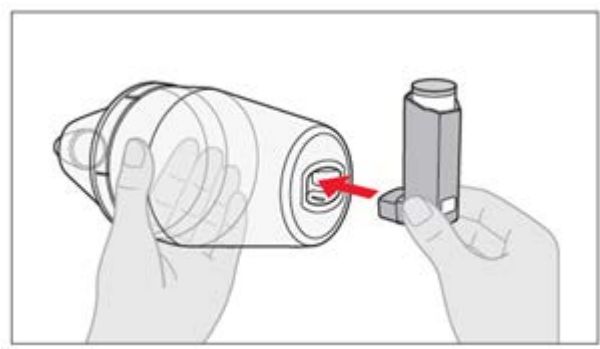
2. Take off the mouthpiece cover from the inhaler and check inside and outside to make sure that the mouthpiece is clean and free of objects. If the inhaler is new or has not been used for a week or more, point the mouthpiece away from you and release one or two puffs into the air.



3. Shake the inhaler 4 or 5 times to ensure that any loose objects are removed and that the contents of the inhaler are well mixed.

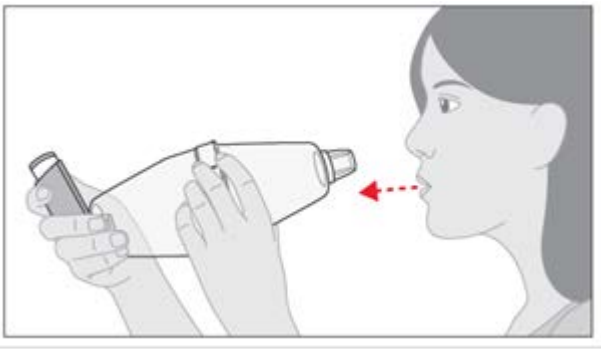


4. Fit the inhaler firmly into the end of the VOLUMATIC Spacer Device, opposite the mouthpiece. Check the mouthpiece of the VOLUMATIC Spacer Device inside and outside to make sure that it is clean.



How to use the VOLUMATIC Spacer Device with your inhaler

5. Hold the device as shown. Breathe out as far as is comfortable.



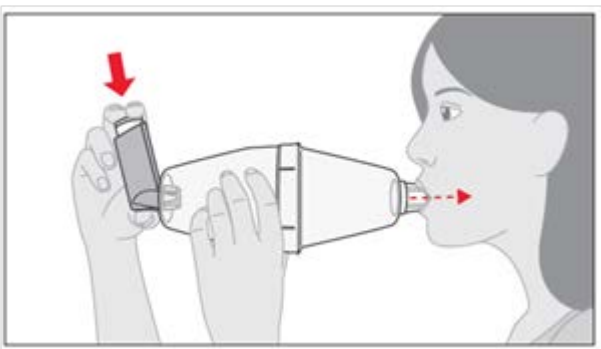
6. Place the mouthpiece in your mouth between your teeth. Close your lips firmly around the mouthpiece but do not bite it.

Do not put your lips over the side holes of the mouthpiece, as the valve will not work.

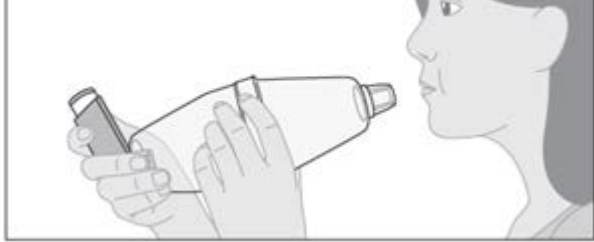


7. Press down with your finger(s) on the top of the inhaler to release one puff of medicine. **Straight away take one deep steady breath or 5 normal breaths to make sure that the medicine goes into your lungs. You do not need to take the VOLUMATIC Spacer Device out of your mouth to breathe out.** You should be able to hear the mouthpiece valve ‘click’ or rattle as you breathe in and out. If you are not able to hear a rattle, hold the VOLUMATIC Spacer Device up at an angle and try again.

Do not squirt all your puffs in to the VOLUMATIC Spacer Device at once and then breathe them in. You must inhale one puff at a time.



8. Hold your breath; take the VOLUMATIC Spacer Device out of your mouth and your finger from the top of the inhaler. Continue holding your breath for a few seconds, or as long as is comfortable.



9. Breathe out.
10. If you need to take more than one puff, remove the inhaler by tilting the top forward and repeat steps 3 to 9. Wait for around 30 seconds before taking each puff of medicine.
11. After use, remove the inhaler from the VOLUMATIC Spacer Device. Replace the mouthpiece cover to keep out dust and fluff.

If you use more than one type of inhaler through the VOLUMATIC Spacer Device repeat the process from step 2. There is no need to wait for more than 30 seconds between inhalers.

If you find it difficult to press down on top of the inhaler when the VOLUMATIC Spacer Device mouthpiece is in your mouth, you may fire a puff into the VOLUMATIC Spacer Device and at once place the VOLUMATIC Spacer Device mouthpiece in your mouth and breathe in (as in Step 7).

If you have been given different instructions for using your VOLUMATIC Spacer Device please follow them carefully.

Tell your doctor, nurse or pharmacist if you have any difficulties using the VOLUMATIC Spacer Device.

REPORTING OF SERIOUS INCIDENTS

Report any serious incident in relation to the VOLUMATIC Spacer Device to the manufacturer. You should also report any serious incident in relation to the VOLUMATIC Spacer device directly to the competent authority (see details below). It is important to report such incidents as this can help identify faults with this medical device and may prevent similar incidents happening again.

United Kingdom

MHRA Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

Ireland

HPRA Pharmacovigilance, Website: www.hpra.ie

4. How to look after your VOLUMATIC Spacer Device

With normal daily use, the VOLUMATIC Spacer Device should be replaced after 12 months of use.

With normal daily use, the VOLUMATIC Spacer Device should be cleaned at least twice a week as follows:

1. Gently pull the two halves of the VOLUMATIC Spacer Device apart. **Do not take the valve apart.**
2. Wash the two halves of the VOLUMATIC Spacer Device in warm water, which can contain a mild detergent or a sterilising solution of the type used to clean babies' bottles. You can use a soft toothbrush or bottlebrush to help remove any film, which forms on the valve or the inside of the VOLUMATIC Spacer Device. As long as the valve still moves when you breathe in and out, this deposit will not affect the working of the VOLUMATIC Spacer Device.
3. Do not rinse the VOLUMATIC Spacer Device parts, as this creates static. Leave the parts at room temperature until they are completely dry. Do not rub the inside of your VOLUMATIC Spacer Device with a cloth or polish, as this may cause static which can affect how the VOLUMATIC Spacer Device works. Do not put the VOLUMATIC Spacer Device in a heated place to dry more quickly.

The VOLUMATIC Spacer Device must not be autoclaved.

4. Reassemble the VOLUMATIC Spacer Device and store in the carton to keep clean and dry.

Ask your pharmacist how to throw away the device you no longer use. This measure will help protect the environment.

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