

Package leaflet: Information for the user

Paediatric VOLUMATIC Spacer Device

Read all of this leaflet carefully before you start using your Paediatric 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 your child. Don't pass it on to other people - it may harm them even if their symptoms seem to be the same as your child's.
- For hygiene reasons, the Paediatric VOLUMATIC Spacer Device must be used by a single patient.
- Do not allow your child to play with the Paediatric VOLUMATIC Spacer Device.

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

In this leaflet:

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

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

A Paediatric VOLUMATIC Spacer Device is a large volume spacer device to help babies and small infants take inhaled medicines. It has a soft face mask which you can place gently over your baby's nose and mouth. The Paediatric VOLUMATIC Spacer Device will help you make sure your baby gets the correct dose of medicine each time.

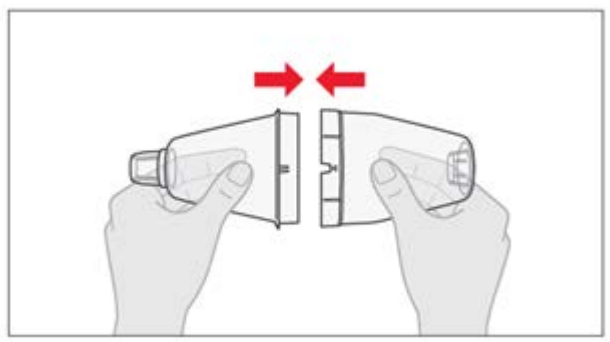
2. Before you use Paediatric VOLUMATIC Spacer Device

Clean the facemask and the Paediatric VOLUMATIC Spacer Device before first use (see the Section "How to look after your Paediatric VOLUMATIC Spacer Device").

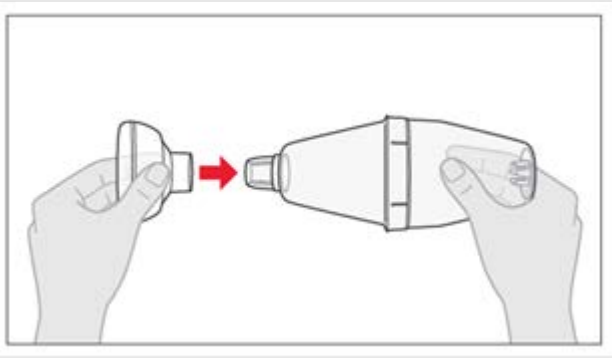
3. How to use the Paediatric VOLUMATIC Spacer Device

How to prepare Paediatric VOLUMATIC Spacer Device for use with the inhaler

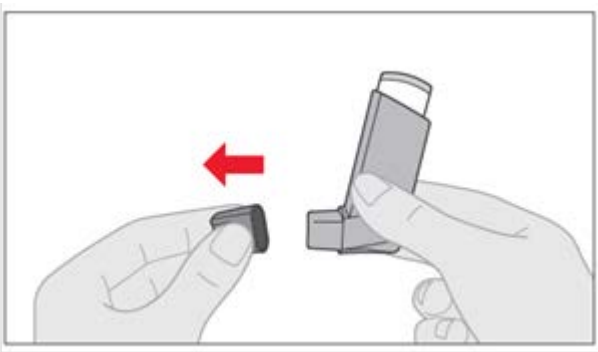
1. Fit the two halves of the Paediatric VOLUMATIC Spacer Device together. Line up the notch on one half with the slot on the other (these are marked with small arrows), then press the two halves firmly together.



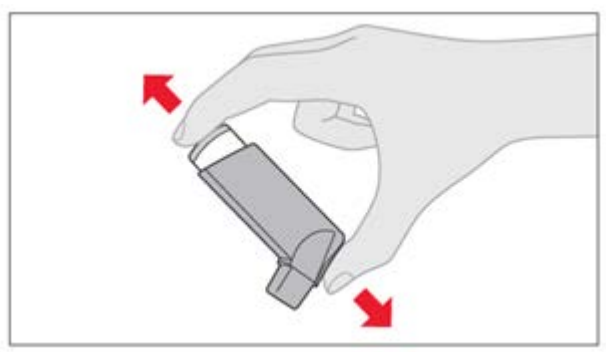
2. Check the mouthpiece of the Paediatric VOLUMATIC Spacer Device inside and outside to make sure that it is clean. Push the face mask firmly onto the Paediatric VOLUMATIC Spacer Device mouthpiece.



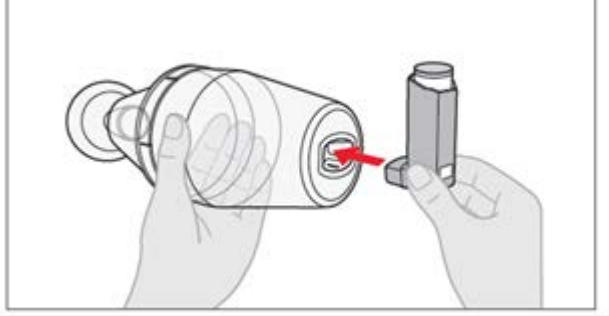
3. Take off the mouthpiece cover from the inhaler and check inside and outside to make sure that the mouthpiece is clean and free of objects. If the inhaler is new or has not been used for a week or more, point the mouthpiece away from you and release one or two puffs into the air.



4. 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.

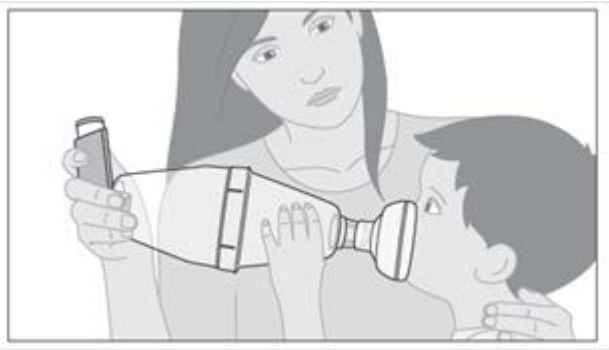


5. Fit the inhaler firmly into the end of the Paediatric VOLUMATIC Spacer Device, opposite the mouthpiece. Check the mouthpiece of the Paediatric VOLUMATIC Spacer Device inside and outside to make sure that it is clean.

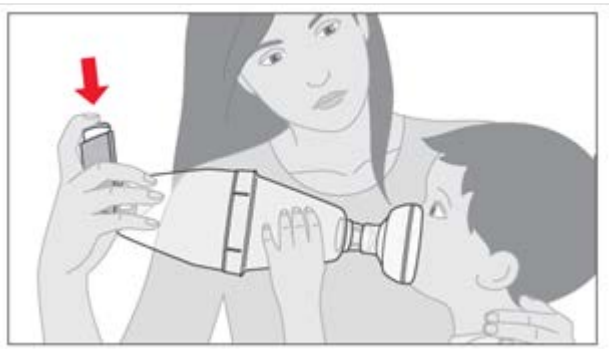


How to use the Paediatric Volumatic Spacer Device with your Inhaler

6. Sit your child comfortably. Babies should lie back in your arms, but children will probably want to sit up. Place the face mask gently over the nose and mouth.



7. Press down on the inhaler to release one puff of medicine into the Paediatric VOLUMATIC Spacer Device. Keep the mask over your child's nose and mouth for at least 10 seconds, and up to 30 seconds if you can, while your child breathes in and out normally. You should be able to hear the mouthpiece valve 'click' or rattle as your child breathes in and out.



Sometimes your child cannot move the valve by breathing, and you will not be able to hear a rattle. In this case hold the Paediatric VOLUMATIC Spacer Device at an angle, allowing the valve to stay open.

If you find it difficult to press down on the inhaler while the mask is over your child's face, release a puff of medicine into the Paediatric VOLUMATIC Spacer Device first and then **immediately** place the face mask over your child's nose and mouth.

8. If your child needs to take more than one puff, shake the inhaler and device well, and repeat step 7. Wait for around 30 seconds before giving each puff of medicine.

Do not squirt all the puffs of medicine into the Paediatric VOLUMATIC Spacer Device at once. Only one puff should be inhaled at a time.

Take the Paediatric VOLUMATIC Spacer Device and face mask away from your child's face.

9. After use, remove the inhaler from the Paediatric VOLUMATIC Spacer Device by tilting the top forwards. Replace the mouthpiece cover to keep out dust and fluff.

If your child uses more than one type of inhaler through the Paediatric VOLUMATIC Spacer Device repeat the process from step 3. There is no need to wait for more than 30 seconds between inhalers.

If you have been given different instructions for using your Paediatric VOLUMATIC Spacer Device please follow them carefully. Tell your doctor, nurse or pharmacist if you have any difficulties using the Paediatric VOLUMATIC Spacer Device.

REPORTING OF SERIOUS INCIDENTS

Report any serious incident in relation to the Paediatric VOLUMATIC Spacer Device to the manufacturer. You should also report any serious incident in relation to the Paediatric 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 Paediatric VOLUMATIC Spacer Device

With normal daily use, the Paediatric VOLUMATIC Spacer Device should be replaced after 12 months of use, and the face mask should be replaced after 6 months of use.

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

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

1. Remove the face mask and inhaler.
2. Gently pull the two halves of the Paediatric VOLUMATIC Spacer Device apart. **Do not take the valve apart.**
3. Wash the face mask and the two halves of the Paediatric 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 Paediatric VOLUMATIC Spacer Device. As long as the valve still moves when your child breathes in and out, this deposit will not affect the working of the Paediatric VOLUMATIC Spacer Device.
4. Rinse the face mask thoroughly in warm water but do not rinse the Paediatric VOLUMATIC Spacer Device parts, as this creates static.
5. Leave the parts at room temperature until they are completely dry. Do not rub the inside of the Paediatric VOLUMATIC Spacer Device with a cloth or polish, as this may cause static which can affect how the Paediatric VOLUMATIC Spacer Device works. Do not put the Paediatric VOLUMATIC Spacer Device in a heated place to dry more quickly.

The VOLUMATIC Spacer Device must not be autoclaved.

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

This leaflet was last revised in March 2021.

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