

Device Identifier 94010  
License 9310

## CONSUMER INFORMATION

### BabyHALER® SPACER DEVICE

Read this carefully before you start using this device. Keep this leaflet. You may need to read it again. If you have further questions, please ask your doctor or your pharmacist.

The medicine for use with this device has been prescribed for your baby, and you should not pass it on to others. It may harm them, even if their symptoms are the same as your baby's.

For hygiene reasons, the BabyHALER® must be used by a single patient.

Do not allow your child to play with the BabyHALER®.

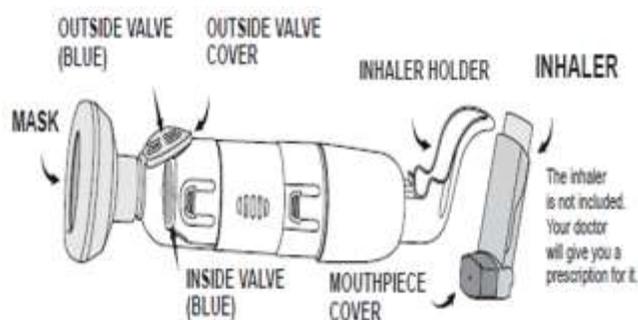
For use only with GlaxoSmithKline FLOVENT® HFA inhaler, as prescribed by your doctor.

The BabyHALER® is not a toy. Do not allow the baby/child to play with the BabyHALER® unsupervised. Small parts may cause harm.

### Your BabyHALER®

A BabyHALER® is a device to help babies and small infants take inhaled medicines. It has a soft facemask which you can place gently over your baby's nose and mouth. The BabyHALER® will help you make sure your baby gets the correct dose of medicine each time.

**PLEASE REFER TO THIS DIAGRAM FOR IDENTIFICATION OF BabyHALER® PARTS**



### How to use your BabyHALER®

Before using the BabyHALER® for the first time, read the following instructions. If you are not sure how to use the BabyHALER®, ask your doctor, nurse or pharmacist. Clean

the BabyHALER® before first use (see the section “How to Clean Your BabyHALER®”).

### Checking the valves

Before you use your BabyHALER®, you need to check that the two blue valves are working properly. Hold the BabyHALER® with the facemask towards you. Press the facemask to your mouth. You should be able to see a part of each of the two blue valves. Very gently breathe in and out through the facemask. When you breathe out, the outside valve at the top of the BabyHALER® should move up slightly. When you breathe in, the inside valve should move towards you slightly. (If this is not happening, see the section “Looking after the valves”).



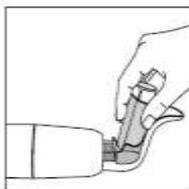
### Preparing the inhaler

**PLEASE TAKE NOTE OF THE PRESCRIBING INFORMATION INDICATED BY YOUR HEALTHCARE PROVIDER.**

1. The BabyHALER® spacer device is intended for use with the inhalation aerosol prescribed by your physician (FLOVENT® HFA).
2. Refer to the inhalation aerosol instructions for proper use of the medication.



3. Remove the mouthpiece cover. Gently fit the inhaler into the BabyHALER® inhaler holder. The mouthpiece of the inhaler should point into the BabyHALER®.



### Giving your baby the medicine

4. Your doctor will have told you how many doses of medicine to give your baby. You should give one dose at a time. Hold your baby and make sure he or she is settled.

5. Keep your BabyHALER<sup>®</sup> level as shown in the photograph. With your thumb, press down once on the inhaler to release a dose of medicine into the BabyHALER<sup>®</sup>, as quickly as possible.



6. Place the facemask gently but securely over your baby's nose and mouth. (Hold the BabyHALER<sup>®</sup> at an angle that is comfortable for both you and your baby.) Keep it there until your baby has taken 5 to 10 breaths (about 15 seconds). You can count the breaths by watching the valves move with each breath. Then take the facemask away from your baby's face.



7. If your doctor has prescribed two doses, repeat steps 6 and 7.

8. Gently wash your baby's face immediately after use.

9. Remove the inhaler from the BabyHALER<sup>®</sup> inhaler holder.

10. Place the BabyHALER<sup>®</sup> back into the protective bag after completing "How to clean your BabyHALER<sup>®</sup>" step.

**If you find it difficult to use your BabyHALER<sup>®</sup> when your baby is awake, you could try using it when he or she is asleep. If you do this, remember that it's important to hold the BabyHALER<sup>®</sup> level when pressing down on the inhaler to release a dose of medicine (see step 6).**

### How to clean your BabyHALER<sup>®</sup>

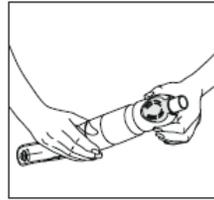
It is **important** to clean your BabyHALER<sup>®</sup> after each use.

### Taking the BabyHALER<sup>®</sup> apart

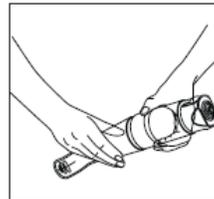
It is **important** to clean your BabyHALER<sup>®</sup> after each use.

1. Check the inhaler is not in the BabyHALER<sup>®</sup>. Gently pull off the soft facemask.

2. Remove the next section by pressing on the two grooved clips with your thumb and fore finger and gently pulling the plastic sections apart.



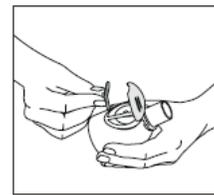
3. To separate the remaining two sections, press on the two grooved clips and gently pull the sections apart.



4. To remove the inside blue valve, pinch it gently at the centre with your thumb and forefinger and take it off its post. To avoid damaging the valves, always handle them very gently and hold them at the centre rather than the edges.



5. To remove the outside blue valve, open the outside valve cover, pinch the blue valve gently at the centre and take it off its post.



6. Clean all the parts using mild soapy water. Rinse the mask thoroughly in warm water but do not rinse BabyHALER® parts as this creates static.

The valves must be handled carefully.

7. Leave the parts at room temperature until they are completely dry. Avoid excessive heat. Don't rub the inside of your BabyHALER® with a cloth or polish as this may cause static which can affect how the BabyHALER® works.

The device must not be autoclaved.

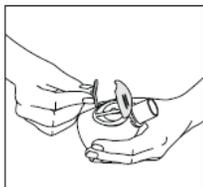
### Reassembling the BabyHALER®

8. Both valves are exactly the same, so it does not matter which one goes where. Pick up one of the valves, holding it at the centre between your thumb and forefinger. Put it on its post on the central section.

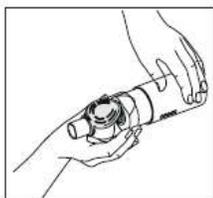


9. Check that the valve is lying flat.

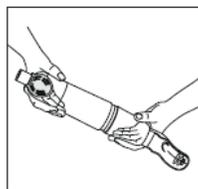
10. Put the other valve on its post. Check that it is lying flat. Close the outside valve cover.



11. Put the two sections with the valves together. Make sure they click shut.



12. Replace the section with the inhaler holder. The two sections should click shut. Make sure that the inhaler holder and the outside valve cover are both pointing upwards.



13. Replace the facemask. If you are not going to use the BabyHALER® immediately, put the device back into its protective bag.

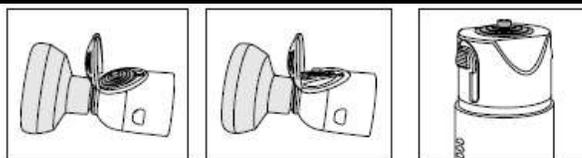
### Looking after the valves

To ensure that your baby gets the correct dose of medicine each time, you must check that the two blue valves in your BabyHALER® are working properly each time you use it. The section “**Checking the valves**” tells you how to do this.

**If a valve is not working properly, it might be because:**

- it is not correctly positioned in your BabyHALER®, or
- it has become worn or damaged and needs to be replaced.

### How to check that the valves are correctly positioned



1. To check the outside valve, lift the outside valve cover and make sure that the valve is lying flat.

2. To check the inside valve, take off the top section of the BabyHALER® by pressing on the grooved clips near the inside blue valve and gently pulling the sections apart. Make sure that the valve is lying flat. Then clip the two sections back together again.

3. Check your BabyHALER® again (see “**Checking the valves**”). If one of the valves is still not working properly, you will need to replace it with a spare valve (see “**How to replace a valve**”).

### How to replace a valve

Two spare valves are included in your BabyHALER® box. All the valves are exactly the same.

1. Remove the faulty valve.
2. Pick up a new valve by pinching it gently at centre with your thumb and forefinger.

3. Put the valve on its post. Check that it is lying flat.
4. Reassemble your BabyHALER®.

### Handling the valves

Always handle the valves carefully. Hold them at the centre rather than at the edges.

Do not expose them to heat or direct sunlight or frost. Do not put them in hot water.

Protect the BabyHALER® from sunlight. You may need to replace your BabyHALER® after 6 months of use.

### MORE INFORMATION

This document can be found at:

<http://www.gsk.ca> or by contacting the sponsor:

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