

**Package leaflet: Information for the user**  
**Respocort™ 50 or 100 micrograms/actuation pressurised inhalation solution**  
**Autohaler™**  
**Beclometasone Dipropionate**

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

- 1. What Respocort Autohaler is and what it is used for**
- 2. What you need to know before you use Respocort Autohaler**
- 3. How to use Respocort Autohaler**
- 4. Possible side effects**
- 5. How to store Respocort Autohaler**
- 6. Contents of pack and other information**

**1. What Respocort Autohaler is and what it is used for**

Respocort Autohaler contains an active ingredient called beclometasone dipropionate. Beclometasone dipropionate is one of a group of medicines known as corticosteroids, which can be used to treat asthma and prevent the symptoms of asthma in patients who require regular treatment.

**How your medicine works**

- Beclometasone dipropionate pressurised inhalation solution works deep in your lungs to make breathing easier by reducing the inflammation, swelling and irritation in the airways. This type of medicine is known as a ‘preventer’. It needs to be taken regularly every day, even if you have no symptoms.
- This inhaler will not give immediate relief of wheezing or breathlessness during a sudden asthma attack. You will need to use a ‘reliever’ inhaler which contains a different medicine. You should still continue to use this inhaler.

**2. What you need to know before you use Respocort Autohaler**

**DO NOT use Respocort Autohaler if you:**

- are allergic to beclometasone dipropionate or any of the other ingredients of this medicine (listed in section 6)

## Warnings and precautions

### Talk to your doctor before you start to take this medicine if:

- you are suffering from tuberculosis (TB) now or have you suffered from it in the past
- you are allergic to other similar inhalers

### Important points to remember while you are using this medicine:

- your doctor may prescribe this inhaler to replace steroid tablets, which may mean that for a short time you have to take both medicines. It is important to follow your doctor's advice. Whilst you are reducing the number of steroid tablets that you take you may feel generally unwell even though you can breathe as well as normal or better. If you have other allergies you may find that stopping your steroid tablets makes them worse. If this happens keep using your inhaler and tell your doctor.
- there may be times when you need to take steroid tablets as well as using your inhaler, for example if you have worsening asthma attacks, you get a chest infection or you need an operation. Your doctor may give you a small supply of steroid tablets to be taken in these situations; if he does you will be given full instructions on how and when to take them. Contact your doctor immediately if you think that you need to take steroid tablets, even if you have your own supply.
- you should have been given a steroid card with this inhaler, if you have not, please ask your pharmacist for one. Make sure you carry your steroid card with you at all times until your doctor decides that it is no longer necessary.
- visit your doctor regularly for a review of your condition.
- contact your doctor if you experience blurred vision or other visual disturbances.
- if you have to go into hospital, remember to take all your inhalers and other medicines with you.

### Other medicines and Respocort Autohaler

- Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines obtained with or without prescription and/or inhalers either prescribed by a doctor or bought from a pharmacy.
- Some medicines may increase the effects of Respocort Autohaler and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

### Pregnancy and breast-feeding

- If you are pregnant, trying to become pregnant or breast feeding a child, ask your doctor for advice before taking this medicine.

### 3. How to use Respocort Autohaler

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or

pharmacist if you are not sure. .

This inhaler has a softer feel and a different taste than CFC inhalers you may have used before. There are two strengths of the *Respocort Autohaler* device available and your doctor will have chosen the strength which best suits your condition. The label should remind you how many puffs to take and how often. Do not take more puffs than your doctor has told you to. It is important that you take your dose as stated on the pharmacist's label or as advised by your doctor. You should not increase or decrease your dose without seeking medical advice. If you are unsure ask your doctor or pharmacist for advice.

This inhaler is an extrafine pressurised inhalation solution which results in more of each dose being delivered to your lungs. Your doctor may, therefore, prescribe a lower dose of this inhaler than your previous CFC beclometasone dipropionate inhaler. Even when your doctor has prescribed a lower dose you may find that the number of puffs you are asked to take from this inhaler is the same as from your previous CFC beclometasone dipropionate inhaler; this is because this inhaler may be a lower strength product (which means that each puff of this new inhaler contains less beclometasone dipropionate than your old CFC beclometasone dipropionate inhaler).

### **The recommended dose is:**

#### **Respocort 50 Autohaler device**

##### **Adults, elderly and children over 12 years**

The starting dose for mild asthma is one puff twice a day. This may be increased up to two puffs twice a day.

The starting dose for moderate asthma is two puffs twice a day. This may be increased up to four puffs twice a day.

For more severe asthma the usual dose is up to eight puffs twice a day.

Your doctor may prescribe up to a total of sixteen puffs per day.

##### **Children under 12 years**

No dosage recommendations are available.

#### **Respocort 100 Autohaler device**

##### **Adults, elderly and children over 12 years**

The starting dose for mild to moderate asthma is one puff twice a day. This may be increased to two puffs twice a day.

For more severe asthma the usual dose is up to four puffs twice a day.

Your doctor may prescribe up to a total of eight puffs per day.

##### **Children under 12 years**

No dosage recommendations are available.

In some circumstances your doctor may prescribe more than the usual number of puffs.

This inhaler must be used regularly, even when you feel well. You must not stop using your inhaler unless your doctor tells you to.

### **If you forget to use your inhaler**

If you forget to use this inhaler at your usual time, take your recommended number of puffs as soon as you remember, then continue to take regularly.

If you think your usual treatment is not working, for example your symptoms are not getting better, or are getting worse, or you need to use more puffs from your reliever inhaler, or if your reliever inhaler does not seem to be working as well as usual, or your peak flow falls, please tell your doctor. Your asthma may be getting worse.

### **If you use more medicine than you should**

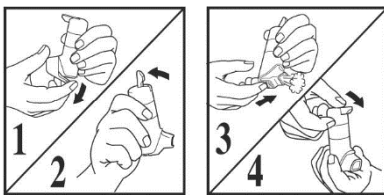
If you accidentally take more puffs than recommended, please tell your doctor.

Ask your doctor for a prescription for a replacement inhaler before this one is empty.

### **Before using this inhaler:**

#### **Before use:**

**If this is a new device or if you have not used it for 2 weeks or more, it must be tested before use by releasing 2 puffs into the air in the following way:**



1. Take the cover off from the mouthpiece, by pulling down on the lip at the back (fig. 1).
2. Point the mouthpiece away from you so that the puffs of medicine will go into the air. Push the lever up so that it stays up (fig. 2).
3. Then, to release a puff, push the dose release slide on the bottom of the device in the direction indicated by the arrow on it (fig. 3).
4. To release the second puff you need to return the lever to its down position (fig. 4) and follow steps 2 and 3 again.

After releasing the second puff, return the lever to its down position, to be ready to take a puff of your medicine.

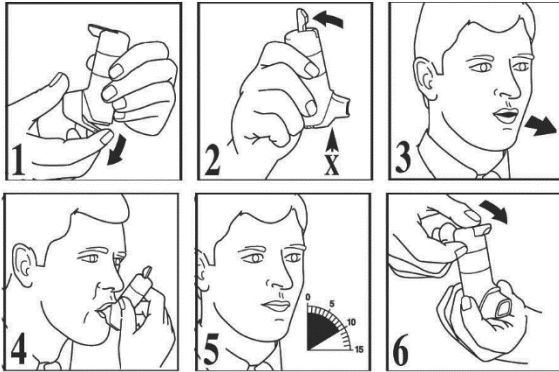
**DO NOT USE THE DOSE RELEASE SLIDE TO TAKE YOUR MEDICINE, THE AUTOHALER DEVICE WILL AUTOMATICALLY RELEASE A DOSE WHEN YOU BEGIN TO BREATHE IN FROM THE MOUTHPIECE.**

The instructions for taking a puff are given below.

### **How to use your Respicort *Autohaler*<sup>TM</sup> device**

1. Take the cover off from the mouthpiece, by pulling down on the lip at the back.
2. Hold your *Autohaler* device upright as shown. Push the lever up so that it stays up. Continue to hold your device upright, making sure that your hand is not blocking the air vent (marked by X in fig. 2) at the bottom of the device.
3. Breathe out as far as is comfortable and then immediately place the mouthpiece in your mouth and close your lips around it.

4. Breathe in slowly and deeply through the mouthpiece. Do not stop breathing in when you hear the slight click and feel the puff in your mouth as it is important that you carry on breathing in after the puff is released.
5. Hold your breath for 10 seconds and then breathe out slowly.
6. The lever must be lowered to the down position after each puff. If your doctor has prescribed more than one puff, repeat steps 2 - 6. After use, replace the cover on the mouthpiece.



#### **How to tell when your *Respicort Autohaler* device is empty**

When the device is completely empty you will not feel or hear any propellant being discharged.

#### **Cleaning instructions**

For normal hygiene, the mouthpiece of your *Autohaler* device should be cleaned weekly with a clean, dry tissue or cloth.

**DO NOT WASH OR PUT ANY PART OF YOUR INHALER IN WATER.**

#### **4. Possible side effects**

Like all medicines, *Respicort Autohaler* can cause side effects, although not everyone gets them. The following side-effects may occur when taking any inhaled medicine containing beclometasone dipropionate:-

Hoarseness, a sore mouth or thrush (white spots in mouth and throat). These are less likely if you rinse your mouth out with water after using your inhaler. If you get thrush talk to your doctor who may recommend a medicine to treat you.

A sore and inflamed throat (pharyngitis), coughing or increased symptoms of asthma.

Feeling of sickness or altered taste after inhaling this medicine.

Headaches, dizziness (vertigo), trembling or shaking.

Hypersensitivity (allergic) reactions such as rashes, itching, redness and swelling of the lips, mouth, throat and eyes may occur. If you experience any of these effects you should see your doctor as soon as possible.

Treatment with *Respicort Autohaler* devices may affect the normal production of corticosteroids in the body. If you become unwell, particularly with abdominal pain, weakness or vomiting, you should see your doctor. This is especially important if you have been exposed to other illness, surgery or infection. At high doses, taken for prolonged periods, bone thinning, clouding of the lens of the eye (cataract) resulting in blurred vision, or loss of vision due to abnormally high pressure in the eye may occur. Children or adolescents who are using the inhaler for a prolonged period may grow more slowly. Your doctor may therefore wish to monitor the height of a child receiving prolonged treatment with *Respicort Autohaler* devices.

*Frequency not known, but may also occur:*

Sleeping problems, depression or feeling worried, restless, nervous, over-excited or irritable. These

effects are more like to occur in children.

**Important:** if immediately after taking a puff of this inhaler you feel wheezy or tight chested do not take any more puffs. Use your reliever inhaler to help your breathing and contact your doctor straight away.

### **Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Respocort Autohaler**

Keep this medicine out of sight and reach of children.

You can use your inhaler at temperatures as low as -10°C.

Do not store your inhaler above 25°C. Avoid storage in direct sunlight or heat. Protect from frost.

The canister is pressurised and should not be punctured or burnt even if it seems empty.

Do not use this inhaler after the date (shown as 'EXP') on the carton and label.

If your doctor decides to stop treatment, return the inhaler to your doctor or pharmacist for safe disposal.

**CAUTION:** Do not push a drying cloth or anything else into any part of the *Autohaler* device since it may cause damage to its operating parts.  
Do not take the *Autohaler* device apart.

## **6. Contents of pack and other information**

### **What Respocort Autohaler contains:**

- The active ingredient is beclometasone dipropionate.
- The other ingredients are propellant HFA-134a and ethanol.
- The name of your medicine is Respocort 50 micrograms/actuation pressurised inhalation solution Autohaler or Respocort 100 micrograms/actuation pressurised inhalation solution Autohaler device depending on which strength your doctor has prescribed for you. These are its brand names, its common name is beclometasone dipropionate pressurised inhalation solution.

### **What Respocort Autohaler looks like and contents of the packs**

- The Respocort Autohaler is a breath-actuated device with a pressurised canister fitted with a metering valve.
- The Respocort 50 Autohaler device delivers 50 micrograms of beclometasone dipropionate per puff (actuation).
- The Respocort 100 Autohaler device delivers 100 micrograms of beclometasone dipropionate per puff (actuation).
- Your inhaler contains 100 or 200 puffs.

Chlorofluorocarbons (CFCs) have been shown to damage the ozone layer in the atmosphere. Your *Respocort Autohaler* device does not contain CFCs, instead the inhaler contains a hydrofluoroalkane (called propellant HFA-134a or Norflurane) as an inactive ingredient. Hydrofluoroalkanes have been developed as a replacement for CFCs because they do not damage the ozone layer.

## **Marketing Authorisation Holder and Manufacturer**

The marketing authorisation holder is

### **Kindeva Drug Delivery Limited**

Loughborough LE11 5SF

United Kingdom

## **Who produces your medication**

*Respocort Autohaler* devices are made by the product licence holder; Kindeva Drug Delivery Limited, Loughborough, Leicestershire, LE11 5SF, United Kingdom.

**This leaflet was last revised in** October 2020.

For further information about asthma, contact the National Asthma Campaign, the independent UK charity working to conquer asthma:

National Asthma Campaign, Providence House, Providence Place, London N1 0NT.

Asthma Helpline: 0345 010203 (Open Monday to Friday, 9am to 7pm. All calls charged at local rates.).

Or visit the National Asthma Campaign's web site - <http://www.asthma.org.uk>

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