

## Package leaflet: Information for the patient

### **DuoResp Spiromax 160 micrograms/4.5 micrograms, inhalation powder** (budesonide/formoterol fumarate dihydrate)

**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, pharmacist or nurse.
- 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 DuoResp Spiromax is and what it is used for
2. What you need to know before you use DuoResp Spiromax
3. How to use DuoResp Spiromax
4. Possible side effects
5. How to store DuoResp Spiromax
6. Contents of the pack and other information

#### **1. What DuoResp Spiromax is and what it is used for**

DuoResp Spiromax contains two different active substances: budesonide and formoterol fumarate dihydrate.

- Budesonide belongs to a group of medicines called ‘corticosteroids’ also known as ‘steroids’. It works by reducing and preventing swelling and inflammation in your lungs and helps you to breathe more easily.
- Formoterol fumarate dihydrate belongs to a group of medicines called ‘long-acting  $\beta_2$  adrenoceptor agonists’ or ‘bronchodilators’. It works by relaxing the muscles in your airways. This will help to open the airways and help you to breathe more easily.

**DuoResp Spiromax is indicated for use in adults 18 years of age and older only.**

**DuoResp Spiromax is NOT indicated for use in children 12 years of age and younger or adolescents 13 to 17 years of age.**

Your doctor has prescribed this medicine to treat asthma or chronic obstructive pulmonary disease (COPD).

#### **Asthma**

DuoResp Spiromax can be prescribed for asthma in two different ways.

**a) You may be prescribed two asthma inhalers: DuoResp Spiromax together with a separate ‘reliever inhaler’ such as salbutamol.**

- Use DuoResp Spiromax every day. This helps to prevent asthma symptoms such as breathlessness and wheezing from occurring.
- Use the ‘reliever inhaler’ when you get asthma symptoms, to make it easier to breathe again.

**b) You may be prescribed DuoResp Spiromax as your only asthma inhaler.**

- Use DuoResp Spiromax every day. This helps to prevent asthma symptoms such as breathlessness and wheezing from occurring.
- Use DuoResp Spiromax when you need to take extra inhalations or puffs to relieve asthma symptoms and to make it easier to breathe again. You do not need a separate ‘reliever inhaler’ for this.

## **Chronic obstructive pulmonary disease (COPD)**

COPD is a long-term lung disease of the airways in the lungs, which is often caused by cigarette smoking. Symptoms include shortness of breath, cough, chest discomfort and coughing up mucus. DuoResp Spiromax can also be used to treat the symptoms of severe COPD in adults.

## **2. What you need to know before you use DuoResp Spiromax**

### **Do not use DuoResp Spiromax if:**

You are allergic to budesonide, formoterol fumarate dihydrate, or the other ingredient in this medicine (listed in section 6).

### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking DuoResp Spiromax if

- you are diabetic.
- you have a lung infection.
- you have high blood pressure or you have ever had a heart problem (including an uneven heartbeat, a very fast pulse, narrowing of the arteries or heart failure).
- you have problems with your thyroid or adrenal glands.
- you have low levels of potassium in your blood.
- you have severe liver problems.

If you have been taking steroid tablets for your asthma or COPD, your doctor may reduce the number of tablets that you take, once you start to use DuoResp Spiromax. If you have been taking steroid tablets for a long time, your doctor may want you to have regular blood tests. When reducing steroid tablets, you may feel generally unwell even though your chest symptoms may be improving. You might experience symptoms such as a stuffy or runny nose, weakness or joint or muscle pain and rash (eczema). If any of these symptoms bother you, or if symptoms such as headache, tiredness, nausea (feeling sick) or vomiting (being sick) occur, please contact your doctor **immediately**. You may need to take other medicines if you develop allergic or arthritic symptoms. You should speak to your doctor if you are concerned as to whether you should continue to use DuoResp Spiromax.

Your doctor may consider adding steroid tablets to your usual treatment during periods of stress (for example, when you have a chest infection or before an operation).

Contact your doctor if you experience blurred vision or other visual disturbances.

### **Children and adolescents**

**This medicine should not be used in children or adolescents under the age of 18 years.**

### **Other medicines and DuoResp Spiromax**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- $\beta$  blockers (such as atenolol or propranolol for high blood pressure or a heart condition), including eyedrops (such as timolol for glaucoma).
- Medicines for a fast or uneven heartbeat (such as quinidine).
- Medicines like digoxin, often used to treat heart failure.
- Diuretics, also known as 'water tablets' (such as furosemide). These are used to treat high blood pressure.
- Steroid medicines that you take by mouth (such as prednisolone).
- Xanthine medicines (such as theophylline or aminophylline). These are often used to treat asthma.
- Other bronchodilators (such as salbutamol).
- Tricyclic antidepressants (such as amitriptyline) and the antidepressant nefazodone.

- Phenothiazine medicines (such as chlorpromazine and prochlorperazine).
- Medicines called ‘HIV protease inhibitors’ (such as ritonavir) to treat HIV infection.
- Medicines to treat infections (such as ketoconazole, itraconazole, voriconazole, posaconazole, clarithromycin and telithromycin).
- Medicines for Parkinson’s disease (such as levodopa).
- Medicines for thyroid problems (such as levothyroxine).

Some medicines may increase the effects of DuoResp Spiromax and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

If any of the above applies to you, or if you are not sure, talk to your doctor, pharmacist or nurse before using DuoResp Spiromax.

Also tell your doctor, pharmacist or nurse if you are going to have a general anaesthetic for an operation or for dental work.

### **Pregnancy, breast-feeding and fertility**

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before taking DuoResp Spiromax - do NOT use this medicine unless your doctor tells you to.
- If you get pregnant while using DuoResp Spiromax, do NOT stop using DuoResp Spiromax but talk to your doctor **immediately**.

### **Driving and using machines**

DuoResp Spiromax is not likely to affect your ability to drive or to use tools or machines.

### **DuoResp Spiromax contains lactose**

Lactose is a type of sugar found in milk. Lactose contains small amounts of milk protein which may cause allergic reactions. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before using this medicine.

## **3. How to use DuoResp Spiromax**

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor, pharmacist or nurse if you are not sure.

- It is important to use DuoResp Spiromax every day, even if you have no asthma or COPD symptoms at the time.
- If you are using DuoResp Spiromax for asthma, your doctor will want to regularly check your symptoms.

### **Asthma**

DuoResp Spiromax can be prescribed for asthma in two different ways. The amount of DuoResp Spiromax to use and when to use it depends on how it has been prescribed for you.

- If you have been prescribed DuoResp Spiromax and a separate reliever inhaler, read the section called **(A) Using DuoResp Spiromax and a separate ‘reliever inhaler’**.
- If you have been prescribed DuoResp Spiromax as your only inhaler, read the section called **(B) Using DuoResp Spiromax as your only asthma inhaler**.

#### **(A) Using DuoResp Spiromax and a separate ‘reliever inhaler’**

**Use your DuoResp Spiromax every day.** This helps to prevent asthma symptoms from occurring.

**Recommended dose:**

Adults (18 years and older)

1 or 2 inhalations (actuations), twice a day.

Your doctor may increase this to 4 inhalations, twice a day.

If your symptoms are well controlled, your doctor may ask you to take your medicine once a day.

Your doctor will help you to manage your asthma and will adjust the dose of this medicine to the lowest dose that controls your asthma. If your doctor feels that you need a lower dose than is available from your DuoResp Spiromax, your doctor may prescribe an alternative inhaler containing the same active substances as your DuoResp Spiromax but with a lower dose of the corticosteroid. However, do not adjust the number of inhalations your doctor has prescribed without talking to your doctor first.

**Use your separate ‘reliever inhaler’ to treat asthma symptoms when they happen.**

Always keep your ‘reliever inhaler’ with you and use it to relieve sudden attacks of breathlessness and wheezing. Do not use DuoResp Spiromax to treat these asthma symptoms.

**(B) Using DuoResp Spiromax as your only asthma inhaler**

Only use DuoResp Spiromax in this way if your doctor has told you to.

**Use your DuoResp Spiromax every day.** This helps to prevent asthma symptoms from occurring.

**Recommended dose**

Adults (18 years and older)

1 inhalation in the morning **and** 1 inhalation in the evening

or

2 inhalations in the morning

or

2 inhalations in the evening.

Your doctor may increase this to 2 inhalations twice a day.

**Also use DuoResp Spiromax as a ‘reliever inhaler’ to treat asthma symptoms when they occur.**

- If you get asthma symptoms such as sudden attacks of breathlessness and wheezing, take 1 inhalation and wait a few minutes.
- If you do not feel better, take another inhalation.
- Do NOT take more than 6 inhalations at a single time.

Always keep your DuoResp Spiromax with you and use it to relieve sudden attacks of breathlessness and wheezing.

A total daily dose of more than 8 inhalations is not normally needed. However, your doctor may allow you to take up to 12 inhalations a day for a limited period.

If you regularly need to use 8 or more inhalations a day, make an appointment to see your doctor. They may need to change your treatment.

Do NOT use more than 12 inhalations in total in 24 hours.

If you are doing exercise and you get asthma symptoms, use DuoResp Spiromax as described here. However, do not use DuoResp Spiromax just before exercise to stop asthma symptoms from happening.

**Chronic Obstructive Pulmonary Disease (COPD)****Recommended dose:**

Adults (18 years and older):

2 inhalations twice a day.

Your doctor may also prescribe another bronchodilator medicine, for example an anticholinergic (such as tiotropium or ipratropium bromide) for your COPD disease.

### Preparing your new DuoResp Spiromax

Before using your DuoResp Spiromax **for the first time**, you need to prepare it for use as follows:

- Open the foil pouch by tearing at the notch at the top of the foil pouch and take out the inhaler
- Check the dose indicator to see that there are 120 inhalations in the inhaler.
- Write the date you opened the foil pouch on the label of the inhaler.
- Do not shake your inhaler before use.

### How to take an inhalation

Every time you need to take an inhalation, follow the instructions below.

1. **Hold your inhaler** with the semi-transparent wine red mouthpiece cover at the bottom.

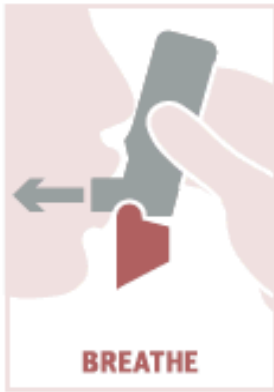


2. Open the mouthpiece cover by folding it down until one loud click is heard. Your medicine is actively metered. Your inhaler is now ready for use.



3. Breathe out gently (as far as is comfortable). Do not breathe out through your inhaler.
4. Place the mouthpiece between your teeth. Do not bite the mouthpiece. Close your lips around the mouthpiece. Take care not to block the air vents.

Breathe in through your mouth as deeply and as hard as you can.



5. Remove your inhaler from your mouth. You may notice a taste when you take your inhalation.

6. Hold your breath for 10 seconds or as long as you comfortably can.

7. **Then breathe out gently** (do not breathe out through the inhaler). **Close the mouthpiece cover.**



If you are to take a second inhalation, repeat steps 1 to 7.

Rinse your mouth with water after every dose, and spit it out.

Do not try to take your inhaler apart, remove or twist the mouthpiece cover, it is fixed to your inhaler and must not be taken off. Do not use your Spiromax if it has been damaged or if the mouthpiece has come apart from your Spiromax. Do not open and close the mouthpiece cover unless you are about to use your inhaler.

### **Cleaning your Spiromax**

Keep your Spiromax dry and clean.

If necessary you may wipe the mouthpiece of your Spiromax after use with a dry cloth or tissue.

### **When to start using a new Spiromax**

- The dose indicator tells you how many doses (inhalations) are left in your inhaler, starting with 120 inhalations when it is full.



- The dose indicator, on the rear of the device, shows the number of inhalations remaining in even numbers only.
- For inhalations remaining from 20 downwards to '8', '6', '4', '2' the numbers are displayed in red on a white background. When the numbers become red in the window, you should consult your doctor and obtain a new inhaler.

Note:

- The mouthpiece will still 'click' even when your Spiromax is empty. If you open and close the mouthpiece without taking an inhalation the dose indicator will still register it as a count. This dose will be securely held inside the inhaler for when the next inhalation is due. It is impossible to accidentally take extra medicine or a double dose in one inhalation.  
Keep the mouthpiece closed all the time unless you are about to use your inhaler.

### **Important information about your asthma or COPD symptoms**

If you feel you are getting breathless or wheezy while using DuoResp Spiromax, you should continue to use DuoResp Spiromax but go to see your doctor as soon as possible, as you may need additional treatment.

Contact your doctor **immediately** if:

- Your breathing is getting worse or you often wake up at night with breathlessness and wheezing.
- Your chest starts to feel tight in the morning or your chest tightness lasts longer than usual.

These signs could mean that your asthma or COPD is not being properly controlled and you may need different or additional treatment **immediately**.

Once your asthma is well controlled your doctor may consider it appropriate to gradually reduce the dose of DuoResp Spiromax.

### **If you use more DuoResp Spiromax than you should**

It is important that you take your dose as advised by your doctor. You should not exceed your prescribed dose without seeking medical advice.

If you use more DuoResp Spiromax than you should, contact your doctor, pharmacist or nurse for advice. The most common symptoms that may occur after if you use more DuoResp Spiromax than you should are trembling, headache or a rapid heartbeat.

### **If you forget to use DuoResp Spiromax**

If you forget to take a dose, take it as soon as you remember. However do **not** take a double dose to make up for a forgotten dose. If it is nearly time for your next dose just take your next dose at the usual time.

If you become wheezy or breathless, or develop any other symptoms of an asthma attack, **use your 'reliever inhaler'**, then seek medical advice.

### **If you stop using DuoResp Spiromax**

Do not stop using your inhaler without telling your doctor first.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**If any of the following happen to you, stop using DuoResp Spiromax and talk to your doctor immediately:**

**Rare side effects: may affect up to 1 in 1,000 people**

- Swelling of your face, particularly around your mouth (tongue and/or throat and/or difficulty to swallow) or hives together with difficulties to breathe (angioedema) and/or sudden feeling of faintness. This may mean that you are having an allergic reaction, which may also include rash and itching.
- Bronchospasm (tightening of the muscles in the airways which causes wheezing and shortness of breath). If the wheezing comes on suddenly after using this medicine stop using it and talk to your doctor **immediately**.

**Very rare side effects: may affect up to 1 in 10,000 people**

- Sudden acute wheezing and/or shortness of breath immediately after using your inhaler (also referred to as ‘paradoxical bronchospasm’). If either of these symptoms occur, **stop using DuoResp Spiromax straightaway** and use your ‘reliever inhaler’. Contact your doctor **immediately** as you may need to have your treatment changed.

**Other possible side effects:**

**Common: may affect up to 1 in 10 people**

- Palpitations (awareness of your heart beating), trembling or shaking. If these effects occur, they are usually mild and usually disappear as you continue to use DuoResp Spiromax.
- Thrush (a fungal infection) in the mouth. This is less likely to occur if you rinse your mouth out with water after using your medicine.
- Mild sore throat, coughing and a hoarse voice.
- Headache.
- Pneumonia (infection to the lung) in COPD patients.

Tell your doctor if you have any of the following while taking DuoResp Spiromax they could be symptoms of a lung infection:

- Fever or chills
- Increased mucus production, change in mucus colour
- Increased cough or increased breathing difficulties

**Uncommon: may affect up to 1 in 100 people**

- Feeling restless, nervous, agitated, anxious or angry.
- Disturbed sleep.
- Feeling dizzy.
- Nausea (feeling sick).
- Fast heartbeat.
- Bruising of the skin.
- Muscle cramps.
- Blurred vision.

**Rare:**

- Low levels of potassium in your blood.
- Uneven heartbeat.

**Very rare:**

- Depression.
- Changes in behaviour, especially in children.
- Chest pain or tightness in the chest (angina pectoris).
- Disturbance of the heart’s electrical system (prolongation of the QTc-interval).
- An increase in the amount of sugar (glucose) in your blood.
- Taste changes, such as an unpleasant taste in the mouth.



- Changes in your blood pressure.
- Inhaled corticosteroids can affect the normal production of steroid hormones in your body, particularly if you use high doses for a long time. The effects include:
- changes in bone mineral density (thinning of the bones)
- cataract (clouding of the lens in the eye)
- glaucoma (increased pressure in the eye)
- a slowing of the rate of growth of children and adolescents
- an effect on the adrenal gland (a small gland next to the kidney)

These effects happen very rarely and are much less likely to happen with inhaled corticosteroids than with corticosteroid tablets.

### Reporting of side effects

If you get any 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 (see details below).

#### United Kingdom

The Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

#### Ireland

HPRA Pharmacovigilance, Earlsfort Terrace, IRL

- Dublin 2; Tel: +353 1 6764971;

Fax: +353 1 6762517.

Website: [www.hpra.ie](http://www.hpra.ie);

E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

#### Malta

ADR Reporting

Website:

[www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal)

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

## 5. How to store DuoResp Spiromax

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton or on the label of your inhaler after EXP. The expiry date refers to the last day of that month.
- Do not store above 25 °C. **Keep the mouthpiece cover closed after removal of the foil wrapping.**
- **Use within 6 months of removing from the foil wrapping.** Use the label on the inhaler to write down the opening date of the foil pouch.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What DuoResp Spiromax contains

- The active substances are budesonide and formoterol fumarate dihydrate. Each delivered (inhaled) dose contains 160 micrograms of budesonide and 4.5 micrograms of formoterol fumarate dihydrate. This is equivalent to a metered dose of 200 micrograms of budesonide and 6 micrograms of formoterol fumarate dihydrate.
- The other ingredient is lactose monohydrate (see section 2 under ‘DuoResp Spiromax contains lactose’)

## What DuoResp Spiromax looks like and contents of the pack

DuoResp Spiromax is an inhalation powder.

Each DuoResp Spiromax inhaler contains 120 inhalations and has a white body with a semi-transparent wine red mouthpiece cover.

Packs of 1, 2, and 3 inhalers. Not all pack sizes may be marketed in your country.

### Marketing Authorisation Holder

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### Manufacturer

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**This leaflet was last revised in May 2017.**

#### **Other sources of information**

Detailed information on this medicine is available on the European Medicines Agency web site:  
<http://www.ema.europa.eu>.