GoResp®digihaler®

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 GoResp Digihaler is and what it is used for

GoResp Digihaler 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 β_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.

GoResp Digihaler is indicated for use in adults 18 years of age and older only.
GoResp Digihaler is NOT indicated for use in children, 12 years of age and younger or adolescents, 13 to 17 years of age.

GoResp Digihaler contains a built-in electronic module, which records and stores information on your inhaler usage. This information can then be transmitted from the inhaler to the Digihaler Mobile Application (App) through Bluetooth® wireless technology. The Digihaler App can be downloaded from the relevant mobile application store onto a smart device. Once the App is downloaded and installed, follow the instructions within the App on how to scan the Quick Response Code (QR code) at the top of the inhaler, in order to link your inhaler with the App.

GoResp Digihaler does not need to be connected to the App in order for you to take your medicine. The electronic module does not control or interfere with the delivery of the medication through the inhaler.

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

Asthma
When used for asthma, your doctor will prescribe GoResp Digihaler together with a separate 'reliever inhaler' such as salbutamol.

- Use GoResp Digihaler 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.

Do not use GoResp Digihaler 320/9 micrograms as a 'reliever inhaler'.

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. GoResp Digihaler can also be used to treat the symptoms of severe COPD in adults.

2. What you need to know before you use GoResp Digihaler

Do not use GoResp Digihaler 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 GoResp Digihaler 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.
- you regularly drink alcohol.

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 GoResp Digihaler. 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 GoResp Digihaler.

Your doctor may consider adding steroid tablets to your usual treatment if you have an illness such as a chest infection or before an operation.

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

Children and adolescents
Do not give this medicine to children or adolescents under the age of 18 years.

Other medicines and GoResp Digihaler
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:
- β blockers (such as atenolol or propranolol for high blood pressure or a heart condition), including eyedrops (such as timolol for glaucoma).
- Oxytocin which is given to pregnant women to induce labour.
- Medicines for a fast or uneven heartbeat (such as quinidine, disopyramide, procinamide and terfenadine).
- 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 tablets 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.
- Antidepressant medicines such as monoamine oxidase inhibitors and those with similar properties (such as the antibiotic furazolidone and the chemotherapy medicine procarbazine).
- Antipsychotic 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 GoResp Digihaler 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 GoResp Digihaler.

Also tell your doctor, pharmacist or nurse if you are going to have a general anaesthetic for an operation or for dental work to help lower any risk of interaction with the anesthetic you receive.

Pregnancy and breast-feeding
- 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 GoResp Digihaler - do NOT use this medicine unless your doctor tells you to.
- If you get pregnant while using GoResp Digihaler, do NOT stop using GoResp Digihaler but talk to your doctor **immediately.**

Driving and using machines
GoResp Digihaler is not likely to affect your ability to drive or to use tools or machines.

GoResp Digihaler contains lactose
Lactose is a type of sugar found in milk. 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 GoResp Digihaler

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 GoResp Digihaler every day, even if you have no asthma or COPD symptoms at the time.
- If you are using GoResp Digihaler for asthma, your doctor will want to regularly check your symptoms.

Asthma
Use your GoResp Digihaler every day. This helps to prevent asthma symptoms from occurring.
Recommended dose:
Adults (18 years and older):
1 inhalation (actuation), twice a day, taken in the morning and in the evening
Your doctor may increase this to 2 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 GoResp Digihaler, your doctor may prescribe an alternative inhaler containing the same active substances as your GoResp Digihaler 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.
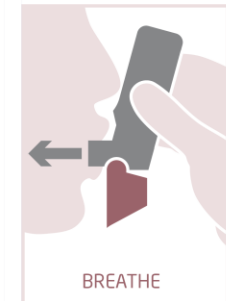Always keep your 'reliever inhaler' with you and use it to relieve sudden attacks of breathlessness and wheezing. Do not use GoResp Digihaler to treat these asthma symptoms.

Chronic Obstructive Pulmonary Disease (COPD)
Recommended dose:
Adults (18 years and older):
- 1 inhalation twice a day, taken in the morning and in the evening.

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 GoResp Digihaler
Before using your GoResp Digihaler **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 90 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.

If you have installed the Digihaler App on a smart device (refer to Section 1), you can register your inhaler in the App.
Follow the App instructions to scan the QR code on the top of your inhaler in order to pair it with the App via Bluetooth.
A message confirming the data has been received by the App may not show up immediately in your smart device. You might need to open the App to see the messages.
Please note, even if you do not scan the QR code or pair with the App, your inhaler will still provide the required dose.

How to take an inhalation
Every time you need to take an inhalation, follow the instructions below.
Please note, for the data to be recorded electronically, use your GoResp Digihaler within one minute of opening the wine red mouthpiece cover. After one minute, you can still take your medication but the data recorded in the App will show low/no inhalation, even if you perform a good or fair inhalation. It is important you remember to close the mouthpiece cover after taking an inhalation.

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.

AIR VENT
Do not block

OPEN

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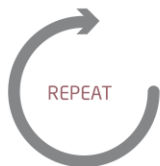
Breathe in through your mouth as deeply and as hard as you can.

BREATHE

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.**

CLOSE

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

REPEAT

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 Digihaler if it has been damaged or if the mouthpiece has come apart from your Digihaler. Do not open and close the mouthpiece cover unless you are about to use your inhaler.

Cleaning your Digihaler
Keep your Digihaler dry and clean.
If necessary you may wipe the mouthpiece of your Digihaler after use with a dry cloth or tissue.
Do not immerse your inhaler in water.

When to start using a new Digihaler
• The dose indicator tells you how many doses (inhalations) are left in your inhaler, starting with 90 inhalations when it is full and ending with 0 (zero) inhalations when it is empty.

• The dose indicator, on the rear of the device, shows the number of inhalations remaining as even numbers. The spaces between the even numbers represent the odd number of remaining inhalations.
• 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 Digihaler 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.

• For more information and customer support service, please visit: www.tevadigihaler.co.uk.

Important information about your asthma or COPD symptoms
If you feel you are getting breathless or wheezy while using GoResp Digihaler, you should continue to use GoResp Digihaler 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 GoResp Digihaler.

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

If you forget to use GoResp Digihaler
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 GoResp Digihaler
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 GoResp Digihaler 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** (see below).

Very rare side effects: may affect up to 1 in 10,000 people
• Sudden, unexpected and 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 GoResp Digihaler straightaway** and use your 'reliever inhaler' if you have one. 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 GoResp Digihaler.
• 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 GoResp Digihaler 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 which does not cause symptoms (prolongation of the QTc-interval).
• An increase in the amount of sugar (glucose) in your blood, when you have a blood test.
• 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). Symptoms of adrenal gland suppression could be tiredness, weakness, stomach problems, including nausea, vomiting, pain and diarrhoea, darkening of the skin and weight loss.

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 via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store GoResp Digihaler

• 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℃. **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 date you open the foil pouch.
• **Do not immerse the inhaler in water.**
• GoResp Digihaler contains a lithium-manganese dioxide battery and must not be thrown away via wastewater or household waste. Ask your pharmacist what to do with your GoResp Digihaler after use or visit www.tevadigihaler.co.uk for more information. These measures will help protect the environment.

6. Contents of the pack and other information

What GoResp Digihaler contains
• The active substances are budesonide and formoterol fumarate dihydrate. Each delivered (inhaled) dose contains 320 micrograms of budesonide and 9 micrograms of formoterol fumarate dihydrate. This is equivalent to a metered dose of 400 micrograms of budesonide and 12 micrograms of formoterol fumarate dihydrate.
• The other ingredient is lactose monohydrate (see section 2 under 'GoResp Digihaler contains lactose').

What GoResp Digihaler looks like and contents of the pack
GoResp Digihaler is an inhalation powder.
Each GoResp Digihaler inhaler contains 90 inhalations and has a white body (with built-in electronic module)

and a semi-transparent wine red mouthpiece cover. The top of the inhaler has a QR code that can be scanned with a smart device to connect to the Digihaler App.

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

The below symbols appear on the inhaler (laser printed) or on the labelling:

 Read the IFU before use symbol

 Degree of protection of applied parts against electric shock

FCC ID: 2AJVSPDR0000401
Federal Communications Commission Identification

 Battery disposal

 Bluetooth transmitter symbol

Marketing Authorisation Holder
Teva UK Limited,
Ridings Point,
Whistler Drive,
Castleford, WF10 5HX,
United Kingdom

Manufacturer
Norton (Waterford) Limited,
Unit 27/35, IDA Industrial Park, Cork Road, Waterford,
Ireland

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Further information about GoResp Digihaler:
The Bluetooth® word mark and logos are registered trademarks owned by the Bluetooth SIG, Inc. and any use of such marks by Teva Respiratory, LLC is under license.
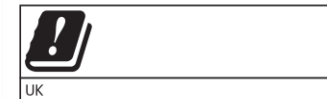
This device has been tested to EN IEC 60601-1-2:2015 +A1:2021 to the requirements for home health care for both emissions and immunity. *Note that portable RF (Radio Frequency) communications equipment, including peripherals such as antenna cables and external antenna, should be used no closer than 30cm (12 inches) to the inhaler whilst the inhaler is being used. Otherwise, registering the use of the inhaler might be delayed or not recorded. You may need to open the app later to see such notifications.*

The inhaler and its associated app running on a smart device are intended for use in the home healthcare environment. *Note that the inhaler can be used in an aircraft, but the smart device should be in "aircraft/flight mode" when required by the cabin crew.*

Do not bring your inhaler(s) into an MRI or CT/X-ray scan room. Do not expose your inhaler to other known sources of electromagnetic interference (such as diathermy). Your inhaler can be taken through standard security systems, such as metal detectors.

IP22 Protected against solid objects over 12.5 mm and direct sprays of water up to 15° from the vertical

UK

 For England, Scotland and Wales Hereby, TEVA declares that the Bluetooth radio equipment contained in this product complies with the requirements of the UK Radio Equipment Regulations (2017). The full text of the UKCA declaration of conformity is available at the following internet address: www.tevadigihaler.co.uk

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