

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**  
The medicine is dispensed with a doctor's prescription only

# DuoResp® Spiromax® 160 mcg/4.5 mcg

## Powder for inhalation

### Composition

Each inhalation contains:  
Budesonide 160 micrograms  
Formoterol fumarate dihydrate 4.5 micrograms

For inactive ingredients, please see section 6 – “Further Information”. Also see “**Important information about some of the ingredients of the medicine**” in section 2.

Each inhaler contains 120 inhalations.

**Read the leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist. Keep the leaflet; you may need it again. This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

This medicine is not intended for children and adolescents under 12 years of age.  
Treatment with DuoResp Spiromax in patients with chronic obstructive pulmonary disease (COPD) is intended for adult patients (from age 18 and above) only.

### 1. WHAT IS THE MEDICINE INTENDED FOR?

DuoResp Spiromax 160 mcg/4.5 mcg is an inhaler intended for the treatment of asthma in adults and adolescents, between the ages of 12-17.

This medicine is also used for symptomatic treatment of COPD in adult patients above the age of 18 only.  
COPD is a chronic disease characterized by a continuous disturbance of airflow into and out of the lungs, and is usually caused by cigarette smoking.

### Therapeutic group

Budesonide – a medicine that belongs to a group called corticosteroids. This medicine helps reduce and prevent swelling and inflammation in the lungs.  
Formoterol fumarate dihydrate – a medicine that belongs to the group called beta 2 agonists/bronchodilators. This medicine helps breathing by relaxing the muscles in the respiratory system and has long-acting activity.

### 2. BEFORE USING THE MEDICINE

#### ☒ Do not use the medicine if:

you are allergic to the active ingredients or to any of the inactive ingredients (see section 6), including lactose (which contains a small amount of milk proteins).

#### Special warnings regarding use of the medicine

#### ☒ Important information regarding symptoms of COPD and asthma:

If you experience shortness of breath or wheezing while using DuoResp Spiromax, continue using the medicine and refer to a doctor as soon as possible; you may need additional treatment.

#### Refer to the doctor immediately in the following cases:

- Worsening of breathing difficulties or if you frequently wake up at night with asthma.
- Chest tightness every morning, or that tightness in the chest lasts longer than usual.

These signs may indicate that your COPD or asthma is not under control and that you may immediately need alternative or additional treatment.

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

#### ☒ Before treatment with DuoResp Spiromax 160 mcg/4.5 mcg, tell the doctor if:

- you are diabetic
- you have pneumonia
- you have hypertension or you have or have ever had a heart disease (including an irregular or rapid pulse, narrowing of the arteries or heart failure)
- you have problems with your thyroid or adrenal glands
- you have low levels of potassium in the blood
- you have severe liver problems

#### ☒ Drug interactions

**If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.** In particular, inform the doctor or pharmacist if you are taking:

- medicines from the beta blocker group used to treat high blood pressure (such as atenolol, propranolol), including eye drops, such as timolol for the treatment of glaucoma.
- antidepressants from the tricyclic group such as amitriptyline, and antidepressants such as nefazodone.
- phenothiazines (such as chlorpromazine and prochlorperazine).
- medicines for treating fast or irregular heart rate (such as quinidine), or for heart failure (such as digoxin).
- oral steroids (such as prednisolone).

- medicines that contain xanthines such as – aminophylline or theophylline, which are usually used to treat asthma.
- medicines called HIV protease inhibitors (such as ritonavir) to treat HIV infection (immunodeficiency disease).
- medicines to treat infectious diseases (such as itraconazole, ketoconazole, voriconazole, posaconazole, clarithromycin, and telithromycin).
- diuretics to treat high blood pressure (such as furosemide).
- other bronchodilators (such as salbutamol).
- medicines to treat Parkinson's disease (such as Levodopa).
- medicines for thyroid problems (such as L-thyroxine).
- Also tell the doctor if you are planning to undergo surgery or dental treatment that requires general anesthesia.

#### ☒ Pregnancy and breastfeeding

- If you are pregnant, or are planning a pregnancy, consult the doctor before using DuoResp Spiromax 160 mcg/4.5 mcg – do not use the preparation unless the doctor has approved it.
- If you become pregnant while using DuoResp Spiromax 160 mcg/4.5 mcg, do not stop using the preparation; however, contact the doctor immediately.
- If you are breastfeeding, consult the doctor before commencing use of the preparation.

#### ☒ Driving and operating machinery

The medicine has no or a negligible effect on the ability to drive or operate machinery.

#### ☒ Important information about some of the ingredients in the medicine

DuoResp Spiromax 160 mcg/4.5 mcg contains lactose, which is a type of sugar. If you have been told by the doctor that you suffer from an intolerance to certain sugars, consult the doctor before taking this medicine. The amount of lactose in this medicine generally does not cause problems in patients with lactose intolerance. Lactose, one of the inactive ingredients in the preparation, contains a small amount of milk proteins, which can elicit an allergic reaction.

### 3. HOW SHOULD YOU USE THE MEDICINE?

- Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.
- It is important to use DuoResp Spiromax every day, regardless of the appearance of COPD or asthma symptoms.
- If you are using this medicine for asthma, the attending doctor will want to regularly monitor your symptoms.
- Do not exceed the recommended dosage.**

If you are taking tablets containing steroids to treat asthma or COPD, the attending doctor may instruct you to decrease the number of tablets you are taking when you start using DuoResp Spiromax 160 mcg/4.5 mcg. If you are taking steroid tablets for a long period of time, your attending doctor may order blood tests. When reducing the oral steroid dosage, you may feel generally unwell, even though your respiratory system symptoms may be improving. You might experience any of the following symptoms – stuffy or runny nose, weakness or pain in the joints or muscles and skin rash (eczema), or a general unwell feeling. If any of these symptoms bother you, or if you experience headache, tiredness, nausea or vomiting, report to the doctor immediately. You may need to take a different medicine if you develop an allergy or symptoms of arthritis. You should contact the doctor if you are not sure whether you should continue to use DuoResp Spiromax 160 mcg/4.5 mcg in this case.

The doctor may consider adding steroid tablets to your DuoResp Spiromax 160 mcg/4.5 mcg treatment plan, particularly during stressful periods (for instance, if you have a chest infection or before any surgery).

The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally –

#### Dosage for treating asthma

DuoResp Spiromax 160 mcg/4.5 mcg for treatment of asthma can be prescribed in two ways. The manner of use, the amount and the frequency of DuoResp Spiromax 160 mcg/4.5 mcg depend on how the preparation has been prescribed for you:

- The doctor may prescribe DuoResp Spiromax with a supplementary inhaler for you.** In this case, use the supplementary inhaler if you get an asthma attack. **See the “Asthma 1” section.**
- The doctor may prescribe DuoResp Spiromax for you as the only medicine.** In this case, you do not need a supplementary inhaler: DuoResp Spiromax provides rapid relief. **See the “Asthma 2” section.**

#### Asthma 1

Using DuoResp Spiromax 160 mcg/4.5 mcg with a separate supplementary inhaler:

- Use DuoResp Spiromax every day to prevent asthma symptoms from occurring.**
- Use the separate supplementary inhaler when you need to treat asthma attacks.**

	Adults (18 years and above)	Adolescents (12-17 years old)	Children under the age of 12
<b>DuoResp Spiromax 160 mcg/4.5 mcg</b>	<b>1-2 inhalations, twice a day.</b> The doctor may increase this dosage to 4 inhalations, twice a day. If your symptoms are well controlled, the doctor may ask you to take your medicine once a day.	<b>1-2 inhalations, twice a day.</b> If your symptoms are well controlled, your doctor may ask you to take your medicine once a day.	<b>Not for use</b>

Always keep the supplementary inhaler with you for use when necessary. Do not use DuoResp Spiromax to treat asthma symptoms; only use the supplementary inhaler.

#### Asthma 2

If the doctor prescribed for you DuoResp Spiromax 160 mcg/4.5 mcg only, without other inhalers, and you are over the age of 12, use it as follows:

- Use DuoResp Spiromax every day to prevent asthma symptoms from occurring.**
- Use DuoResp Spiromax to relieve asthma attacks, when necessary.**

#### Daily use of DuoResp Spiromax 160 mcg/4.5 mcg:

	Adults	Adolescents above the age of 12	Children under the age of 12
<b>DuoResp Spiromax 160 mcg/4.5 mcg</b>	1 inhalation in the morning and 1 inhalation in the evening or 2 inhalations in the morning or 2 inhalations in the evening The doctor may increase this dosage to 2 inhalations twice a day	1 inhalation in the morning and 1 inhalation in the evening or 2 inhalations in the morning or 2 inhalations in the evening The doctor may increase this dosage to 2 inhalations twice a day	<b>Not for use</b>

#### Use of DuoResp Spiromax 160 mcg/4.5 mcg to relieve asthma attacks, as necessary:

	Adults	Adolescents above the age of 12	Children under the age of 12
<b>DuoResp Spiromax 160 mcg/4.5 mcg</b>	<b>Upon onset of signs of asthma, take one inhalation</b> and wait a few minutes. <b>If you do not feel better</b> , you can take another inhalation.  <b>Do not take more than 6 inhalations at a single time.</b>	<b>Upon onset of signs of asthma, take one inhalation</b> and wait a few minutes. <b>If you do not feel better</b> , you can take another inhalation.  <b>Do not take more than 6 inhalations at a single time.</b>	<b>Not for use</b>

Always keep the supplementary inhaler with you to use when needed.

**A total daily dose of more than 8 inhalations is usually not 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, it is strongly recommended that you refer to the doctor or nurse to make a possible change in your treatment.

Do not take more than 12 inhalations in 24 hours.

If you are doing exercise and experience asthma symptoms, use the inhaler as described in this section. However, do not use DuoResp Spiromax 160 mcg/4.5 mcg before exercise to prevent asthma symptoms from occurring.

#### Treatment of chronic obstructive pulmonary disease (COPD)

##### Allowed for use in adults (aged 18 and above) only

	Adults (18 years and above)	Adolescents (12-17 years old)	Children (6-11 years old)
<b>DuoResp Spiromax 160 mcg/4.5 mcg</b>	<b>2 inhalations, twice a day</b>	<b>Not for use</b>	<b>Not for use</b>

Your doctor may add other bronchodilators to your treatment program for this disease, for example, anticholinergic medicines such as ipratropium bromide.

##### Instructions for use of DuoResp Spiromax

##### How to prepare a new inhaler for use

##### Before using for the first time:

- Open the aluminum wrapper by tearing the slit at the top of the wrapper, and take out the inhaler.
- Make sure that the dose indicator shows 120 doses.
- Record the opening date of the aluminum wrapper on the inhaler sticker.
- Do not shake the inhaler before use.

##### How to inhale

Follow the instructions below:

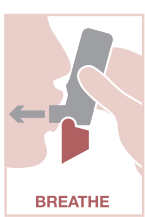
- Hold the inhaler** with the transparent wine-red mouthpiece cover facing downward.



- Remove the mouthpiece cover by folding it down until you hear a loud click. The inhaler is ready for use with a metered dose of the medicine.



- Breathe out gently (as much as you can). Do not breathe out through the inhaler.
- Place the mouthpiece between your teeth. Do not bite the mouthpiece. Close your lips around the mouthpiece. Make sure not to block the air vents.
- Breathe in through your mouth as deeply and forcefully as you can.



- Remove the inhaler from your mouth. You may feel a taste upon taking the inhalation.
- Hold your breath for 10 seconds, or for as long as you can.
- Then, breathe out gently (do not breathe out through the inhaler). Close the mouthpiece cover.



If you are supposed to take a second inhalation, repeat steps 1-8.

Rinse your mouth with water after each dose. Do not swallow. Do not try to take the inhaler apart, remove or twist the mouthpiece cover, since it is fixed to the inhaler and must not be taken off.

Do not use DuoResp Spiromax if it is damaged or if the mouthpiece has fallen off the inhaler. Do not open and close the mouthpiece cover unless you intend to use the inhaler.

#### Cleaning

Keep the inhaler clean and dry.

If necessary, the inhaler mouthpiece can be dried after use with a dry cloth or wipe.

##### When to use a new DuoResp Spiromax inhaler



Duo-Resp Spiromax 160 mcg/4.5 mcg

- The dose indicator shows how many doses (inhalations) remain in the inhaler; at first it shows 120 inhalations when the inhaler is full.
- The dose indicator, which is located at the back of the device, indicates the number of inhalations left, in even numbers only.
- For remaining inhalations, starting from 20 and down until “8”, “6”, “4”, “2”, the numbers appear in red on a white background. When the numbers in the window turn red, refer to a doctor to obtain a new inhaler.

#### Note

- The mouthpiece continues to make a click sound even when the inhaler is empty.
- If you open and close the mouthpiece without taking an inhalation, the indicator will still register that a dose was loaded. The dose is securely stored in the inhaler and is ready for the next inhalation. Neither an additional dose nor a double dose can be taken in a single inhalation.
- Keep the mouthpiece **closed** when the inhaler is not in use.

Use this medicine when treating asthma and chronic obstructive pulmonary disease at set intervals and at the dosages determined by the attending doctor and indicated on the sticker by the pharmacist. An excessive dosage should not be used without prior medical advice.

**If you accidentally took a higher dosage**, you may experience one of the following effects: tremor, headache or palpitations. If you took an overdose or if a child has accidentally taken the medicine, immediately proceed to a hospital emergency room and bring the package of the medicine with you.

**If you forgot a dose of DuoResp Spiromax:** inhale a dose as soon as you remember. If it is very close to the time of the next inhalation, skip the dose. Do not take a double dose to compensate for the forgotten dose.

Adhere to the treatment regimen as recommended by the doctor.

**Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.**

**If you have further questions regarding use of the medicine, consult a doctor or pharmacist.**

#### 4. SIDE EFFECTS

As with any medicine, use of DuoResp Spiromax may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

##### Stop using DuoResp Spiromax 160 mcg/4.5 mcg and refer to a doctor immediately if:

- You experience swelling of the face, particularly around the mouth (swelling of the tongue and/or throat and/or difficulty swallowing), rash or urticaria, together with breathing difficulties (angioedema) and/or suddenly feeling faint. These effects may indicate that you are experiencing an allergic reaction. These effects are rare and affect less than 1 patient in 1,000.
- You experience sudden and acute wheezing or shortness of breath immediately after using the inhaler. If any of these symptoms occur, stop using DuoResp Spiromax immediately and use the supplementary inhaler for relief. Contact the attending doctor immediately, as you may need to change the treatment. These effects are very rare and affect less than 1 patient in 10,000.

Additional side effects:

##### Side effects occurring very frequently (affect up to one patient in 10):

- Palpitations (feeling of heart beating), tremor or shaking. If these effects occur, they are usually mild and generally disappear as treatment progresses.
- Mouth sores (oral thrush). The chance of this happening can be reduced by rinsing your mouth each time after you finish using the inhaler.
- Mild sore throat, coughing and a hoarse voice.
- Headache.
- Pneumonia in COPD patients.

Refer to a doctor if you are suffering from one of the following effects that may be a sign of pneumonia:

Fever or chills, change in color or increase in amount of mucus, aggravation of cough or exacerbation of breathing difficulties.

##### Side effects occurring frequently (affect up to one patient in 100):

- Agitation, nervousness or restlessness
- Sleep disturbances
- Dizziness
- Nausea
- Rapid heart rate
- Skin bruises
- Muscle spasms
- Blurred vision

##### Side effects occurring infrequently (affect up to one patient in 1,000):

- Rash and itching
- Low levels of potassium in the blood
- Irregular heartbeat
- Bronchospasm (narrowing of the muscles in the airways causing wheezing). If, immediately after using DuoResp Spiromax, you suddenly start wheezing, stop using the inhaler and contact a doctor immediately.

##### Side effects occurring rarely (affect up to one patient in 10,000):

- Depression
- Behavior disturbances, especially in children
- Chest pain or tightness (angina pectoris)
- Increased blood sugar (glucose) levels
- Taste changes, such as an unpleasant taste in the mouth
- Changes in 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. This effect may be manifested in:

- Changes in bone density (thinning of the bones)
- Cataract (clouding of the lens in the eye)
- Glaucoma (increased intraocular pressure)
- Slowed growth rate of children and adolescents, requiring monitoring by the attending doctor, who may refer the child to a specialist, if necessary.
- An effect on the adrenal gland (a small gland located next to the kidney).

These side effects are more likely to occur with oral corticosteroid treatment (e.g., tablets) as compared to inhaled corticosteroids.

**If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.**

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

### 5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use this medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store below 25°C.
- Keep the mouthpiece closed after removing the aluminum wrapper.
- Can be used for 6 months after removing the aluminum wrapper. It is recommended to use the sticker on the inhaler to record the opening date of the wrapper.
- Do not store different medicines in the same package.
- After using the last dose, throw out the inhaler; do not discard it into the household wastebin. Please consult the pharmacist about how to dispose it.

### 6. FURTHER INFORMATION

**In addition to the active ingredients, the medicine also contains:**

Lactose monohydrate.

**What the medicine looks like and the contents of the package:**

DuoResp Spiromax 160 mcg/4.5 mcg is an inhaler that contains inhalation powder. Each inhaler contains 120 doses in a white container with a transparent wine-red mouthpiece cover.

Each package contains either 1, 2 or 3 inhalers. Not all package sizes may be marketed.

#### Name of License Holder and its address:

Abic Marketing Ltd., P.O.B. 8077, Netanya.

#### Name of Manufacturer and its address:

Norton (Waterford) Ltd., T/A Teva Pharmaceuticals Ireland, Waterford, Ireland.

#### Registration number of the medicine in the National Drug Registry of the Ministry of Health:

154.58.34443

This leaflet was checked and approved by the Ministry of Health in August 2017 and was updated in accordance with the Ministry of Health guidelines in June 2019.

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