

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

DuoResp® Spiromax® 320 mcg/9 mcg Powder for inhalation

Composition
Each inhalation contains:
Budesonide 320 micrograms
Formoterol fumarate dihydrate 9 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 60 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 320 mcg/9 mcg is an inhaler that is used for treatment of asthma in adults and adolescents aged 12-17 years. This medicine is also used for treatment of the symptoms of chronic obstructive pulmonary disease (COPD) in adults aged 18 years and older only.
COPD is a chronic disease characterized by constant disturbances of airflow into and out of the lungs, and is usually caused by cigarette smoking.
This medicine can be prescribed in different ways for different patients.

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 a 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 or 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 the 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 320 mcg/9 mcg, tell the doctor if:
• you are diabetic.
• you suffer or have suffered in the past from a heart problem (including an irregular heartbeat, a rapid pulse, narrowing of arteries, or heart failure).
• you suffer from hypertension.
• you suffer from low levels of potassium in the blood.
• you suffer from problems with your thyroid gland.

- you suffer from severe liver problems.
- you suffer from pneumonia.
- you suffer from problems with your adrenal gland.

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:
• antidepressants from the tricyclic group (such as amitriptyline), and antidepressants such as nefazodone.
• phenothiazines (such as chlorpromazine and prochlorperazine).
• beta blockers taken orally (such as atenolol, or propranolol for hypertension) or in eye drops (such as timolol for glaucoma).

- medicines for treating fast or irregular heartbeat (such as quinidine), or for heart failure (such as digoxin).
- oral steroids (such as prednisolone).
- xanthine derivatives (for treatment of asthma, such as theophylline or aminophylline).
- medicines called HIV-protease inhibitors (such as ritonavir) for treatment of HIV infection (human immunodeficiency disease).
- medicines for treatment of infections (such as itraconazole, ketoconazole, voriconazole, posaconazole, clarithromycin, telithromycin).
- diuretics (such as furosemide) for treatment of hypertension.
- bronchodilators (such as salbutamol).
- anti-Parkinson's medicines (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 320 mcg/9 mcg – do not use the preparation unless the doctor has approved it.
• If you become pregnant while using DuoResp Spiromax 320 mcg/9 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 your ability to drive or operate machinery.
Important information about some of the ingredients of the medicine
DuoResp Spiromax 320 mcg/9 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 could 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 320 mcg/9 mcg 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 for treatment of asthma or COPD, the attending doctor may instruct you to decrease the number of tablets you are taking when you start using DuoResp Spiromax 320 mcg/9 mcg. If you are taking steroid tablets for a long period of time, your attending doctor may order blood tests to be performed. When reducing the oral steroid dosage, you may feel generally unwell, even though your respiratory system symptoms may be improving. You may experience any of the following symptoms: stuffy or runny nose, weakness or pain in joints or muscles and skin rash (eczema). If any of these symptoms bother you, or if you experience a headache, tiredness, nausea, or vomiting, report to the doctor immediately. You may need to have additional treatment 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 in this case.
The doctor may consider adding steroid tablets to your DuoResp Spiromax 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
Use your inhaler every day to help prevent asthma symptoms from occurring.

Adults (18 years and over)
• The usual dosage is: one inhalation twice a day.
• Some patients may need the maximum dose of up to 2 inhalations twice a day.
• If you feel that your symptoms are under control, your doctor may instruct you to take the medicine **once** a day.

Adolescents (12-17 years old)
• The usual dosage is: one inhalation twice a day.
• If you feel that your symptoms are under control, your doctor may instruct you to take the medicine **once** a day.
Your doctor (or asthma nurse) will help you manage treatment of your asthma. They will adjust the dose of this medicine to the lowest possible dose with which your disease can be controlled. Do not adjust the dose yourself without consulting with your asthma nurse/doctor.

Use the supplementary inhaler to relieve symptoms of your asthma. Always keep your supplementary reliever inhaler with you for use when necessary. Do not use DuoResp Spiromax 320 mcg/90 mcg for relief during an asthma attack; use your supplementary inhaler for relief.

Chronic obstructive pulmonary disease (COPD)
• May be used by adults only (aged 18 and over).
• The usual dosage for adults is one inhalation twice a day.

Your doctor may add to your treatment program other bronchodilator drugs, such as anticholinergics, e.g., tiotropium or 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 60 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:
1. **Hold the inhaler** with the transparent wine-red mouthpiece cover facing downward.

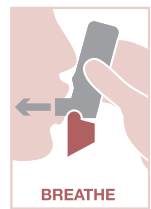


2. Remove the mouthpiece cover by folding it down until you hear a loud click. The inhaler is ready for use with a metered dose of the medicine.



3. Breathe out gently (as much as you can). Do not breathe out through the inhaler.
4. 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.

5. Breathe in through your mouth as deeply and forcefully as you can.



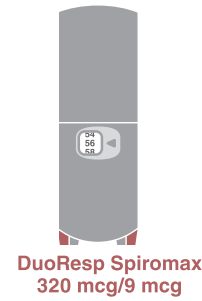
6. Remove the inhaler from your mouth. You may feel a taste upon taking the inhalation.
7. Hold your breath for 10 seconds, or for as long as you can.
8. Then, breathe out gently (do not breathe out through the inhaler). Close the mouthpiece cover.



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 wiped after use with a dry cloth or wipe.

When to use a new DuoResp Spiromax inhaler



- The dose indicator shows how many doses (inhalations) remain in the inhaler; at first it shows 60 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 downwards 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 used 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 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 when reading the list of side effects. You may not suffer from any of them.

Stop using DuoResp Spiromax 320 mcg/9 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 swallowing difficulties), rash or hives (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, they 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, they 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 your heart pounding), tremor or shaking. If these effects occur, they are 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 symptoms of pneumonia: Fever or chills, change in color or an increase in the 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 heartbeat
• 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
• Behavioral 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 steroids 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 of the eye)
• Glaucoma (increased intraocular pressure)
• A slowing in the rate of growth of children and adolescents, requiring monitoring by the attending doctor, who, if necessary, may refer the child to a specialist
• An effect on the adrenal gland (a small gland located next to the kidney)
These effects are more likely to happen with treatment with oral steroids (such as tablets) than with treatment with inhaled steroids.
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) 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 the 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.
• Discard the inhaler after you have used the last dose, do not discard it into the household wastebin. Please consult with your pharmacist on how to dispose of 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 320 mcg/9 mcg is an inhaler that contains inhalation powder. Each inhaler contains 60 doses in a white body with a semi-transparent wine-red mouthpiece cover container.
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:
154.59.34444
The leaflet was revised in June 2019.