

**Patient Package Leaflet in Accordance With
the Pharmacists' Regulations (Preparations) – 1986**

The medicine is dispensed with a doctor's prescription only

**Duaklir® Genuair®
340/12 micrograms
inhalation powder**

Active ingredients:

Each dose for inhalation contains:

396 mcg acclidinium bromide, equivalent to 340 mcg acclidinium and 11.8 mcg formoterol fumarate dihydrate.

For a list of inactive ingredients please refer to Section 6.

See also 'Important information about some of the ingredients of the medicine' in Section 2.

Read this leaflet carefully in its entirety before using the medicine.

Keep this leaflet, you may need it again.

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

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 the age of 18 years.

1. WHAT IS THE MEDICINE INTENDED FOR?

This medicine is used as maintenance bronchodilator treatment in order to relieve symptoms in adults who suffer from COPD (chronic obstructive pulmonary disease). In this disease the airways in the lungs become damaged or blocked. By opening the airways, the medicine helps relieve symptoms such as shortness of breath. Using the inhaler regularly will help to minimise the effects of COPD on your everyday life.

Therapeutic group:

This medicine contains two active ingredients from the bronchodilators group.

Acclidinium bromide: anticholinergic.

Formoterol fumarate dihydrate: beta-agonist (long lasting activity).

2. BEFORE USING THE MEDICINE**Do not use the medicine if:**

you are allergic to the active ingredients (formoterol fumarate dihydrate, acclidinium bromide) or to the other ingredient lactose (see Section 6).

Special warnings regarding use of the medicine:**Before treatment with Duaklir Genuair, tell the doctor if you have:**

- asthma. This medicine should not be used for the treatment of asthma
 - heart problems
 - epilepsy
 - thyroid gland problems (thyrotoxicosis)
 - a tumour in one of your adrenal glands (phaeochromocytoma)
 - difficulty passing urine or problems due to an enlarged prostate
 - narrow angle glaucoma, which results in high pressure in the eye.
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- **Stop treatment and seek medical help immediately in the following situations:**
 - If you have sudden difficulty in breathing or swallowing, if you have swelling of the tongue, throat, lips or face; a skin rash and/or itching. These may be signs of an allergic reaction.
 - If you get sudden tightness of the chest, coughing, wheezing or breathlessness immediately after using the medicine, these may be signs of a condition called “paradoxical bronchospasm” (an excessive and prolonged contraction of the airway muscles immediately following treatment with a bronchodilator).
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- The inhaler is used as a maintenance (long-term) treatment for COPD and is not used to treat a sudden attack of breathlessness or wheezing.

- If your usual COPD symptoms (breathlessness, wheezing, cough) do not improve or get worse, continue use of Duaklir Genuair and refer to your doctor as soon as possible because you may need another medicine.
- If you see halos around lights or colored images, suffer from temporary blurring of vision, or have eye pain or discomfort, refer to your doctor as soon as possible.
- Dry mouth has been observed with medicines like Duaklir Genuair. Pay attention to oral hygiene as it may cause dry mouth which in the long-term can be associated with tooth decay.

Children and adolescents

This medicine is not intended for children or adolescents under the age of 18.

Drug interactions:

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

- Other medicines that may be similar to Duaklir Genuair to treat breathing difficulties.
- Medicines that may lower the amount of potassium in your blood such as:
 - corticosteroids that you take by mouth (such as prednisolone).
 - diuretics (such as furosemide or hydrochlorothiazide).
 - certain medicines used to treat breathing conditions (such as theophylline).
- Medicines called beta blockers that may be used to treat high blood pressure or heart problems (such as atenolol, propranolol) or to treat glaucoma (such as timolol).
- Medicines which can cause a type of change in the electrical activity of the heart (QT interval prolongation) observed in an electrocardiogram (ECG), such as medicines used to treat the following conditions:
 - depression (such as monoamine oxidase inhibitors or tricyclic antidepressants).
 - bacterial infections (such as erythromycin, clarithromycin, telithromycin).
 - allergic reactions (anti-histamines).

Use of the medicine with food and drinks

You can take this medicine at any time (before or after food or drinks).

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning a pregnancy, consult your doctor before using this medicine. You should not use this medicine if you are pregnant or breast-feeding without consulting your doctor.

Driving and using machines

It is unlikely that the medicine will affect your ability to drive or use machines. Still, in some patients, this medicine may cause blurred vision or dizziness. If you are affected by either of these side effects, do not drive or use machines until the dizziness has cleared and your vision has returned to normal.

Important information about some of the ingredients of the medicine

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking this medicine (see Section 6).

3. HOW SHOULD YOU USE THIS MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and manner of treatment with this medicine.

The dosage and course of treatment will be determined only by the doctor.

- **The recommended dose is usually:** one inhalation twice a day: one in the morning and one in the evening.
- The effects of the medicine last for 12 hours; therefore, it is recommended to use the inhaler at the same time each morning and evening as this will ensure that there is always enough medicine in your body to help you breathe more easily throughout the day and night. Taking your medicine at regular times will also help you to remember to use it.
- Duaklir Genuair is for inhalation use.

- Instructions for use of the Genuair inhaler: Carefully read the instructions at the end of this leaflet before using the inhaler. If you are not sure how to use the inhaler, contact your doctor or pharmacist.

COPD is a long-term disease, Duaklir Genuair is for long-term use. Therefore, Duaklir Genuair must be used every day, twice a day, and not only when breathing problems or other symptoms of COPD are experienced.

The recommended dose can be used for elderly patients and for patients with kidney or liver problems. No dose adjustments are necessary in these patients.

Do not exceed the recommended dose.

If you use more Duaklir Genuair than you should

If you think you may have used a larger dosage than you should, you are more likely to experience some of its side effects, such as: blurred vision, dry mouth, feeling sick, shaking/tremor, headache, palpitations or an increase in blood pressure. Therefore refer immediately to your doctor or hospital emergency room and bring the package of the medicine with you. You may need medical attention.

If you forget to use the inhaler

If you forget a dose of Duaklir Genuair, take the dose as soon as you remember and take your next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

Continue treatment as recommended by the doctor.

Even if there is an improvement in your health, do not discontinue treatment with the medicine without consulting your doctor or pharmacist.

If you stop using the medicine

This medicine is for long-term use. If you want to stop using the medicine, first consult with your doctor, as your symptoms may worsen.

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

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

4. SIDE EFFECTS

As with any medicine, use of Duaklir Genuair 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.

Uncommon Side Effects (occurring in up to 1 of 100 patients):

- Muscle weakness, twitching and/or abnormal heart rhythm: these may be signs of a decrease in the amount of potassium in your blood.
- Tiredness, increased thirst and/or a need to pass urine more frequently than usual: these may be signs of an increase in the amount of sugar in your blood.
- Palpitations, as these may be a sign of an unusually fast heartbeat or an abnormal heart rhythm.

Rare Side Effects (occurring in up to 1 of 1,000 patients):

- Sudden difficulty in breathing or swallowing, swelling of the tongue, throat, lips or face; skin rash and/or itching- these may be signs of an allergic reaction.

Other side effects:

Common Side Effects (occurring in up to 1 of 10 patients):

- Combination of sore throat and runny nose (these may be signs of nasopharyngitis)
- Headache
- Painful and/or frequent urination (these may be signs of a urinary tract infection)
- Cough
- Diarrhea
- A blocked, runny or stuffy nose and/or pain or a feeling of pressure in the cheeks or forehead (these may be signs of sinusitis)
- Dizziness

- Muscle cramps
- Nausea
- Difficulty sleeping
- Dry mouth
- Muscle pain
- Abscess (infection) in the tissues at the base of a tooth
- High blood levels of a protein found in muscle called creatine phosphokinase
- Shaking/tremor
- Anxiety

Uncommon Side Effects (occurring in up to 1 of 100 patients):

- Fast heart beat (tachycardia)
- Chest pain or tightness in the chest (angina pectoris)
- Blurred vision
- Changes in the sound of the voice (dysphonia)
- Difficulty passing urine or a feeling that your bladder has not completely emptied (urinary retention)
- An abnormal heart rate (QT interval prolongation)
- Distorted sense of taste
- Throat irritation
- Inflammation of the mouth (stomatitis)
- Increased blood pressure
- Agitation
- Rash
- Itching of the skin

If a side effects occurs, if any side effect get worse, or if you suffer from a side effect not mentioned in the leaflet, consult your doctor.

Reporting of side effects

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 TO STORE THE MEDICINE?

- 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 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.
- Storage conditions: Store below 30°C.
- The inhaler should be used within 60 days of opening the aluminum pouch and no later than the expiry date of the product.
- Keep the inhaler protected inside the original pouch until the beginning of use.
- Do not use the inhaler if you notice that the pack is damaged.
- After you have taken the last dose, the inhaler has to be disposed of. Ask your pharmacist how to throw it away.

6. FURTHER INFORMATION

In addition to the active ingredients, the medicine also contains the inactive ingredient lactose monohydrate.

Each measured dose contains 11.6 mg lactose monohydrate.

What the medicine looks like and contents of the pack?

The medicine found in Duaklir Genuair is a white or almost white powder.

The Genuair inhaler is a white device fitted with an integral dose indicator and an orange dosage button. The mouthpiece is covered with a removable orange protective cap.

The inhaler is supplied in a sealed protective aluminium pouch containing a desiccant sachet and packaged in a carton. After removing the inhaler from the aluminium bag, the aluminium bag and desiccant sachet should be thrown away.

The inhaler contains 60 doses.

License Holder:

AstraZeneca (Israel) Ltd.,

1 Atirei Yeda St., Kfar Saba 4464301.

Manufacturer:

Industrias Farmacéuticas Almirall, S.A., Spain.

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

155-38-34337-00

Revised on August 2022 according to MoH guidelines.

INSTRUCTIONS FOR USE OF THE DUAKLIR GENUAIR INHALER

This section contains information on how to use Genuair inhaler. It is important that you read this information as the Genuair may work differently from inhalers you have used previously.

If you have any questions about how to use your inhaler, please ask your doctor, pharmacist or nurse for assistance.

The Instructions for Use is divided into the following sections:

- Getting started
- Step 1: Prepare your dose
- Step 2: Inhale your medicine
- Additional information

Getting Started

Before using the Duaklir Genuair inhaler, please read the instructions below.

Become familiar with the parts of the inhaler:

Control window.
Green = inhaler ready
for use

Dose
indicator

Orange
button

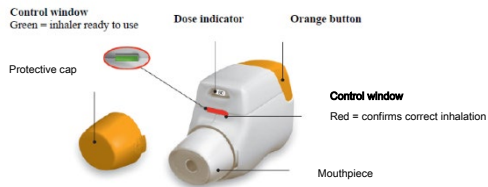


Figure 1

1. Before first use, tear open the sealed bag and remove the inhaler. Throw away the bag and desiccant sachet.
2. Do not press the orange button until you are ready to take a dose.
3. Remove the protective cap from the mouthpiece by lightly squeezing the arrows marked on each side of the cap (see Figure 2).



Figure 2

STEP 1: Prepare your dose

- 1.1 Look in the opening of the mouthpiece and make sure nothing is blocking it (Figure 3).
- 1.2 Look at the control window, it should be red (Figure 3).

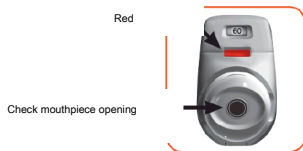


Figure 3

- 1.3 Hold the inhaler horizontally with the mouthpiece facing you and the orange button on top (Figure 4).



Figure 4

1.4 Press the orange button all the way down to load your dose. When you press the button all the way down, the control window changes from red to green (Figure 5).

Make sure the orange button is on top. **Do not tilt the inhaler.**

1.5 Release the orange button (Figure 6).

Make sure you release the orange button, so the inhaler can work correctly.



Figure 5 **Figure 6**

Stop and Check:

1.6 Make sure the control window is now green (Figure 7).

Your medicine is ready to be inhaled.

Go to 'STEP 2: Inhale your medicine'.

Green



Figure 7

What do you need to do if the control window is still red after pressing the button? (Figure 8).



Figure 8

The dose is not prepared. Go back to 'STEP 1 Prepare your dose' and repeat steps 1.1 to 1.6.

STEP 2: Inhale your medicine

Read steps 2.1 to 2.7 fully before use. Do not tilt the inhaler.

2.1 Hold the inhaler away from your mouth and breathe out completely. Never breathe out into the inhaler (Figure 9).



Figure 9

2.2 Hold your head upright, put the mouthpiece between your lips, and close your lips tightly around it.

Do not hold the orange button down while inhaling.



Figure 10

2.3 Take a strong, deep breath through your mouth. Keep breathing in for as long as possible.

A 'click' will let you know that you are inhaling correctly. Keep breathing in as long as possible after you hear the 'click'. Some patients may not hear the 'click'. Use the control window to ensure you have inhaled correctly.

2.4 Take the inhaler out of your mouth.

2.5 Hold your breath for as long as possible.

2.6 Slowly breathe out away from the inhaler.

Some patients may experience a grainy sensation in their mouth, or a slightly sweet or bitter taste. Do not take an extra dose even if you do not taste or feel anything after inhaling.

Stop and Check:

2.7 Make sure the control window is now red (Figure 11). This means you have inhaled your medicine correctly.



Figure 11

What to do if the control window is still green after inhalation (Figure 12).



Figure 12

This means you have not inhaled your medicine correctly. **Go back to 'STEP 2 Inhale your medicine' and repeat steps 2.1 to 2.7.**

If the control window still does not change to red, you may have forgotten to release the orange button before inhaling, or you may not have inhaled strongly enough. If this happens, try again. Make sure you have released the orange button, and you have breathed out completely. Then take a strong, deep breath through the mouthpiece.

Please contact your doctor if the control window is still green after repeated attempts.

Push the protective cap back onto the mouthpiece after each use (Figure 13), to prevent contamination of the inhaler with dust or other materials. You should discard your inhaler if you lose the cap.



Figure 13

Additional information

What should you do if you accidentally prepare a dose?

Store your inhaler with the protective cap in place until it is time to inhale your medicine, then remove the cap and start at Step 1.6.

How does the dose indicator work?

- The dose indicator shows the total number of doses left in the inhaler (Figure 14).
- On first use, every inhaler contains at least 60 doses.
- Each time you load a dose by pressing the orange button, the dose indicator moves by a small amount towards the next number (50, 40, 30, 20, 10, or 0).

When should you change to a new inhaler?

You should get a new inhaler:

- If your inhaler appears to be damaged or if you lose the cap
- When a red band appears in the dose indicator, this means you are nearing your last dose (Figure 14)
- If your inhaler is empty (Figure 15).

Dose indicator moves slowly from 60 to 0: 60, 50, 40, 30, 20, 10, 0



Figure 14

How do you know that your inhaler is empty?

When the orange button will not return to its full upper position and is locked in a middle position, you have reached the last dose (Figure 15). Even though the orange button is locked, your last dose may still be inhaled. After that, the inhaler cannot be used again and you should start using a new inhaler.

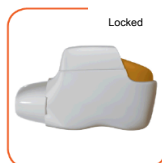


Figure 15

How should you clean the inhaler?

NEVER use water to clean the inhaler, as this may damage your medicine.

If you wish to clean your inhaler, just wipe the outside of the mouthpiece with a dry tissue or paper towel.