

Patient Leaflet According to the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Eklira® Genuair®

Powder for inhalation

Active ingredient:

Each delivered dose contains 375 mcg of aclidinium bromide equivalent to 322 mcg of aclidinium.

For a list of inactive ingredients, please see section 6.

Also see 'Important information about some of the medicine's ingredients' in section 2.

Read this entire leaflet carefully before using this medicine.

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

This medicine has been prescribed for the treatment of your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

This medicine is not intended for children and adolescents under 18 years of age.

1. What is the medicine intended for?

This medicine is indicated for maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD (chronic obstructive pulmonary disease), a serious, longterm lung disease characterised by breathing difficulties.

Regular use of Eklira inhaler can help you when you have ongoing shortness of breath related to your disease and will help you to minimise the effects of the disease on your everyday life.

Therapeutic group:

Anticholinergics, bronchodilators.

2. Before you use the medicine

X Do not use this medicine if:

- Do not use if you are sensitive (allergic) to the active ingredient or to any of the other ingredients of this medicine (for a list of inactive ingredients, please see section 6).

Special warnings regarding the use of this medicine:

¶ Before the treatment with Eklira tell your doctor:

- if you have had heart problems recently.
- if you see halos around lights or coloured images (glaucoma).
- if you have an enlarged prostate, problems passing urine, or a blockage in your bladder.

Eklira is indicated for maintenance treatment and the inhaler is not intended for the treatment of a sudden attack of breathlessness or wheezing. If the symptoms of your illness (breathlessness, wheezing, coughing) do not improve or worsen - refer to your doctor as soon as possible.

Pay attention to oral hygiene, since the medicine may cause dry mouth, which in long term use may cause tooth decay.

If you feel chest tightness, wheezing, breathlessness or coughing right after using this medicine - stop the treatment and seek medical assistance immediately. These symptoms can be a sign of bronchospasm.

¶ Use in children and adolescents

This medicine is not intended for children and adolescents under 18 years of age.

¶ If you are taking or have recently taken any other medicines, including non-prescription medicines and nutrition supplements, please tell your doctor or pharmacist. Especially inform your doctor or pharmacist if you are taking the following medicines:

- similar medicines for the treatment of breathing problems, such as medicines containing tiotropium, ipratropium: the use of Eklira in combination with these medicines is not recommended.

¶ Use of this medicine with food and drink

You can use this medicine anytime (before or after food or drink).

! Pregnancy and breastfeeding

If you are pregnant, planning to become pregnant, suspect that you are pregnant, or if you are breastfeeding, consult your doctor before using this medicine. You should not use the medicine if you are pregnant or are breast-feeding without consulting your doctor.

! Driving and use of machinery

The medicine may have minor influence on the ability to drive or operate machinery. This medicine may cause headache, dizziness or blurred vision. If you experience these effects - do not drive or operate machinery until the headache has cleared, the feeling of dizziness has passed and your vision has returned to normal.

! Important information about some of the medicine's ingredients

This medicine contains lactose. If you have been told by your doctor that you are sensitive to some sugars, inform your doctor before using this medicine (see section 6).

3. How to use this medicine?

Always use according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure.

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

- The standard dosage 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 your inhaler at the same time every morning and evening. This ensures that there is always enough medicine in your body to help you breathe more easily throughout the day and night. It will also help you to remember to use it.

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

COPD is a long-term disease; therefore, it is recommended that Eklira Genuair is used every day, twice a day and not only when breathing problems or other symptoms of COPD are experienced.

Do not exceed the recommended dose.

- **Instructions for use of Genuair inhaler:** Read the instructions carefully before using the inhaler. If you are not sure of how to use the inhaler, contact your doctor or pharmacist.

If you use more Eklira Genuair than you should, if you think you may have used a higher dosage, contact your doctor or pharmacist.

If you forgot to use this medicine at the set time, use it immediately as soon as you remember. If it is almost time for the next dose, skip the forgotten dose. Do not take a double dose to compensate for the forgotten dose.

Continue with the treatment as recommended by your doctor.

Even if your state of health improves, do not stop the treatment with this medicine without consulting your doctor or a pharmacist.

If you stop using the medicine: This medicine is intended for long term treatment. If you stop using this medicine, the symptoms of your disease may worsen. If you wish to stop using this medicine, consult your doctor.

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

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

4. Side effects:

Like any medicine, the use of Eklira may cause side effects in some users. Do not be alarmed while reading the list of side effects, you may not suffer from any of them.

Stop the treatment and seek medical assistance immediately in the following cases:

- If right after using this medicine you feel chest tightness, wheezing, breathlessness or coughing. See also section 'Special warnings regarding the

use of this medicine'.

- Allergic reactions may rarely occur (may affect up to 1-10 in every 10,000 patients). Stop using the medicine and contact your doctor immediately if you develop the following symptoms: swelling of your face, throat, lips or tongue (with or without difficulty breathing or swallowing), feeling dizzy or fainting, faster heart rate and/or severely itchy bumps on your skin (hives). These may be symptoms of an allergic reaction.

Common side effects (affect up to 1:10 patients):

Headache; inflammation of the sinuses (sinusitis); common cold (runny nose and inflammation of the nose and pharynx); cough; diarrhoea, nausea.

Uncommon side effects (affect up to 1:100 patients):

Dizziness, dry mouth; Inflammation of the mouth (stomatitis); hoarseness or difficulty speaking due to disturbances of the pharynx, vocal cords, tongue or mouth (dysphonia); fast heart beat (tachycardia); sensation of heart beating (palpitations); urinary retention (difficulty passing urine); blurred vision; rash; itching of the skin.

If the side effects persist, or they are bothersome or get worse, consult your doctor.

In any case you experience side effects not mentioned in this leaflet or if you feel a change in your general feeling, consult your doctor immediately!

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 stored in a safe place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.

- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Storage conditions: There are no special storage conditions, however, it is recommended to store in a cool and dry place.
- After taking out the inhaler from the pouch for the first time it can be used for up to 90 days.
- Keep the inhaler inside the pouch until the beginning of use.
- Do not use the inhaler if you notice that the pack is damaged.
- After you have used the last dose, the inhaler has to be disposed of. Consult your pharmacist how to dispose of it.

6. Additional information

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

Each measured dose contains 12.6 mg of lactose monohydrate.

- **What does the medicine look like and what does the package contain?**

The medicine inside Eklira Genuair is a white or almost white powder.

The inhaler is white with a green dosage button. The protective cap of the mouthpiece is green.

The inhaler is packed in a plastic pouch inside a carton box.

The inhaler contains: 30 or 60 doses. Not all pack sizes may be marketed.

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: 151-70-33997-00

This leaflet was checked and approved by the Ministry of Health in March 2015 and was updated according to Ministry of Health guidelines in December 2018.

Instructions for use:

This section contains information on how to use the 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, refer to your doctor, pharmacist or nurse.

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

Read the Instructions for Use below before you start using the Eklira Genuair inhaler.

Become familiar with the parts of the inhaler:

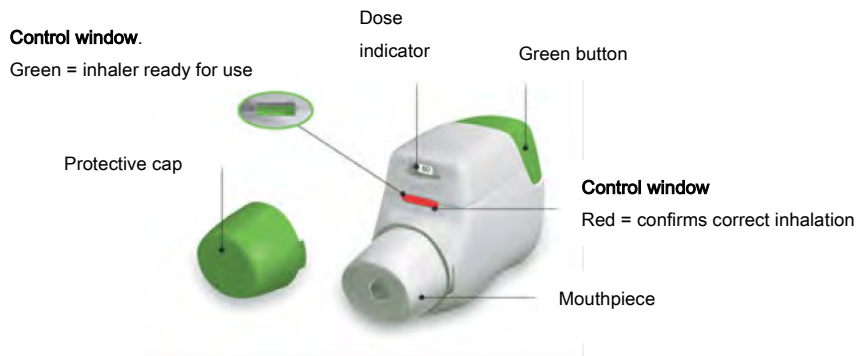


Figure A

Figure 1

1. Before first use, tear open the sealed bag and remove the inhaler. Throw away the bag.

2. Do not press the green button until you are ready to take a dose.
3. Remove the cap from the mouthpiece by lightly squeezing the arrows marked on each side of the cap (Figure 2).

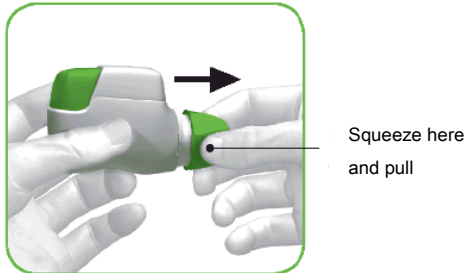


Figure B

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 green button on top (Figure 4).



Figure D

Figure 4

1.4 Press the green 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 green button is on top. **Do not tilt the inhaler.**

1.5 Release the green button (Figure 6).

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



Figure E

Figure 5



Figure F

Figure 6

Stop and Check:

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

Your medicine is ready to be inhaled.

Go to 'STEP 2: Inhale your medicine'.



Figure G

Figure 7

What 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 (Figure 10).

Do not hold the green button down while inhaling.



Figure J
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 the dose.

2.4 Take the inhaler out of your mouth.

2.5 Hold your breath for as long as possible.

2.6 Slowly breathe out.

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 green button before inhaling, or you may not have inhaled strongly enough. If this happens, try again. Make sure you have released the green 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 M

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 green 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, or
- When a **red band** appears in the dose indicator, this means you are nearing your last dose (Figure 14), or
- If your inhaler is empty (Figure 15).

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

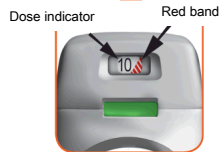


Figure 14

How do you know that your inhaler is empty?

When the green 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 green 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.

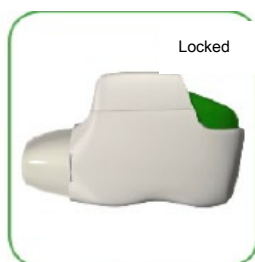


Figure 15

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.