Package leaflet: Information for the patient

Eklira Genuair® 322 micrograms inhalation powder
(aclidinium (aclidinium bromide))

Your medicine is available using the name Eklira Genuair 322 micrograms inhalation powder, but will be referred to as Eklira Genuair throughout this leaflet.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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 Eklira Genuair is and what it is used for**
2. **What you need to know before you use Eklira Genuair**
3. **How to use Eklira Genuair**
4. **Possible side effects**
5. **How to store Eklira Genuair**
6. **Contents of the pack and other information**

Instructions for Use

1. WHAT EKLIRA GENUAIR IS AND WHAT IT IS USED FOR
What Eklira Genuair is
The active ingredient of Eklira Genuair is aclidinium bromide, which belongs to a group of medicines called bronchodilators. Bronchodilators relax airways and help keep bronchioles open. Eklira Genuair is a dry powder inhaler that uses your breath to deliver the medicine directly into your lungs. This makes it easier for chronic obstructive pulmonary disease (COPD) patients to breathe.

What Eklira Genuair is used for
Eklira Genuair is indicated to help open the airways and relieve symptoms of COPD, a serious, long-term lung disease characterised by breathing difficulties. Regular use of Eklira Genuair can help you when you have ongoing shortness of breath related to your disease to help you minimise the effects of the disease on your everyday life and reduce the number of flare-ups (the worsening of your COPD symptoms for several days).

2. WHAT YOU NEED TO KNOW BEFORE YOU USE EKLIRA GENUAIR
Do not use Eklira Genuair
- if you are allergic to aclidinium bromide or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using Eklira Genuair:
- 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 Genuair is indicated for maintenance treatment and should not be used to treat a sudden attack of breathlessness or wheezing. If your COPD symptoms (breathlessness, wheezing, cough) do not improve or get worse you should contact your doctor for advice as soon as possible.

Dry mouth, which has been observed with medicines like Eklira Genuair, may after using your medicine for a long time, be associated with tooth decay. Therefore, please remember to pay attention to oral hygiene.

Stop taking Eklira Genuair and seek medical help immediately:
- if you get tightness of the chest, coughing, wheezing or breathlessness immediately after using the medicine. These may be signs of a condition called bronchospasm.

Children and adolescents
Eklira Genuair is not for use in children or adolescents below 18 years of age.

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

Inform your doctor if you have been or are using similar medicines for breathing problems, such as medicines containing tiotropium, ipratropium. Ask your doctor or pharmacist if you are not sure. The use of Eklira Genuair with these medicines is not recommended.

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 or pharmacist for advice before taking this medicine. You should not use Eklira Genuair if you are pregnant or are breast-feeding unless your doctor tells you so.

Driving and using machines
Eklira Genuair may have minor influence on the ability to drive and use machines. This medicine may cause headache, dizziness or blurred vision. If you are affected by any of these side effects do not drive or use machinery until the headache has cleared, the feeling of dizziness has passed and your vision has returned to normal.

Eklira Genuair contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO USE EKLIRA GENUAIR
Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one inhalation twice a day in the morning and evening.
The effects of Eklira Genuair last for 12 hours; therefore, you should try to use your Eklira Genuair 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.

Route of administration
The medicine is for inhalation use.

Refer to Instructions for Use for instructions on how to use the Genuair inhaler. If you are not sure of how to use Eklira Genuair, contact your doctor or pharmacist.
You can use Eklira Genuair any time before or after food or drink.

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

If you forget to use Eklira Genuair
If you forget a dose of Eklira Genuair, inhale the dose as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop using Eklira Genuair
This medicine is for long-term use. If you want to stop treatment, first talk to your doctor, as your symptoms may worsen. 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.

Allergic reactions may rarely occur (may affect up to 1 in 1,000 people). Stop using the medicine and contact your doctor immediately if you develop swelling of your face, throat, lips or tongue (with or without difficulty breathing or swallowing), dizziness or fainting, faster heart rate or if you get raised severely itchy bumps on your skin (hives) as these may be symptoms of an allergic reaction.

The following side effects may occur whilst using Eklira Genuair:
Common: may affect up to 1 in 10 people
- Headache
- Inflammation of the sinuses (sinusitis)
- Common cold (nasopharyngitis)
- Cough
- Diarrhoea
- Nausea

Uncommon: may affect up to 1 in 100 people
- Dizziness
- Dry mouth
- Inflammation of the mouth (stomatitis)
- Hoarseness (dysphonia)
- Faster heart beat (tachycardia)
- Sensation of heart beating (palpitations)
- Difficulty passing urine (urinary retention)
- Blurred vision
- Rash
- Itching of the skin

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 EKLIRA GENUAIR
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 inhaler label and carton after "EXP". The expiry date refers to the last day of that month.

Keep the inhaler inside the pouch until the administration period starts.

To be used within 90 days of opening the pouch.

Do not use the Eklira Genuair if you notice that the pack is damaged or shows signs of tampering.

After you have taken the last dose, the inhaler has to be disposed of. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION
What Eklira Genuair contains
- The active substance is aclidinium bromide. Each delivered dose contains 375 micrograms aclidinium bromide equivalent to 322 micrograms of aclidinium.
- The other ingredient is lactose monohydrate (refer to Section 2 "Eklira Genuair contains lactose").

What Eklira Genuair looks like and contents of the pack
Eklira Genuair is a white or almost white powder.
The Genuair inhaler device is white coloured with an integral dose indicator and a green dosage button. The mouthpiece is covered with a removable green protective cap. It is supplied in a plastic pouch.

Pack sizes supplied:
Carton containing 1 inhaler with 60 doses.

Not all pack sizes may be marketed.

Manufacturer
Industrias Farmacéuticas Almirall, S.A.
Ctra. Nacional II, Km. 593
08740 Sant Andreu de la Barca, Barcelona
Spain
Or
Industrias Farmacéuticas Almirall, S.A.,
Ctra. De Martorell 41-61,
08740 Sant Andreu de la Barca, Barcelona,
Spain.

Procured from within the EU and repackaged by:
BModesto B.V., Minervaweg 2, 8239 DL, Lelystad, Netherlands.

Product Licence holder: Doncaster Pharma Limited, Crompton Road, Doncaster, DN2 4PW, UK.

PLGB: 56830/0161 POM

Leaflet issue and revision date (Ref.): 13.09.2024

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Blind or partially sighted?
Is this leaflet hard to see or read?
Call +44 (0) 1302 365000 (Regulatory)

Please be ready to give the following information:
Product name: Eklira Genuair
322 micrograms inhalation powder
Reference No: 56830/0161

Please turn over for Instructions for Use ⮌

Instructions for Use

This section contains information on how to use your 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
Read these Instructions for Use before you start using the medicine.
Become familiar with the parts of your Genuair inhaler.

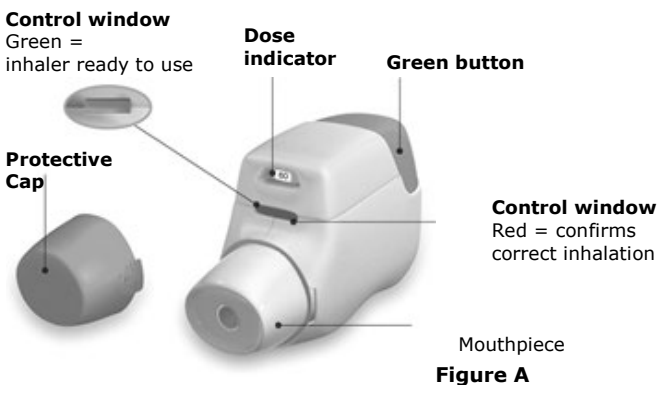


Figure A

Before use:
a) Before first use, tear open the sealed bag and remove the inhaler. Throw away the bag.
b) Do not press the green button until you are ready to take a dose.
c) Pull off the cap by lightly squeezing the arrows marked on each side (Figure B).

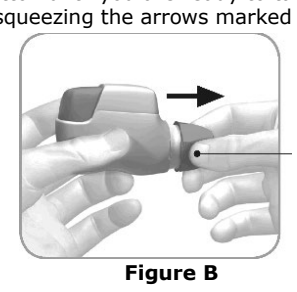


Figure B

STEP 1: Prepare your dose
1.1 Look in the opening of the mouthpiece and make sure nothing is blocking it (Figure C).

1.2 Look at the control window (should be red, Figure C).

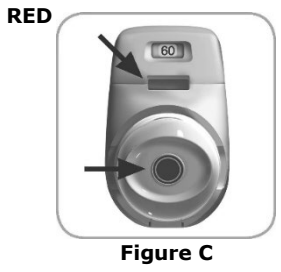


Figure C

1.3 Hold the inhaler horizontally with the mouthpiece facing you and the green button on top (Figure D).

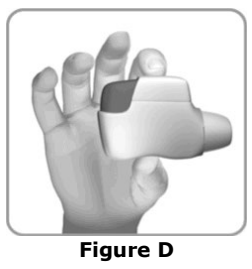


Figure D

1.4 Press the green button all the way down to load your dose (Figure E).

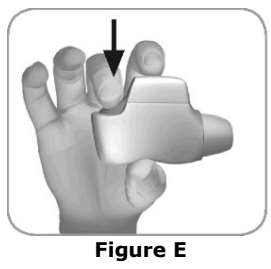


Figure E

When you press the button all the way down, the control window changes from red to green.

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

1.5 Release the green button (Figure F).

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

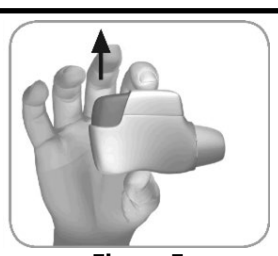


Figure F

Stop and Check:
1.6 Make sure the control window is now green (Figure G).
Your medicine is ready to be inhaled.
Go to 'STEP 2: Inhale your medicine'.



Figure G

What to do if the control window is still red after pressing the button (Figure H).



Figure H

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.

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

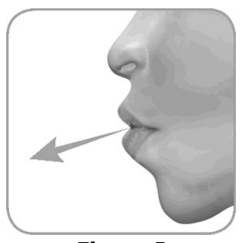


Figure I

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

Do not hold the green button down while inhaling.



Figure J

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 K). This means you have inhaled your medicine correctly.

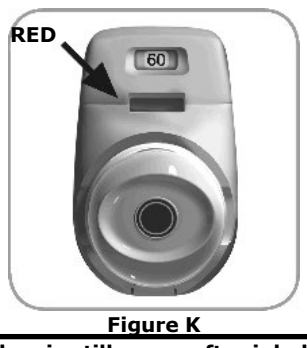


Figure K

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

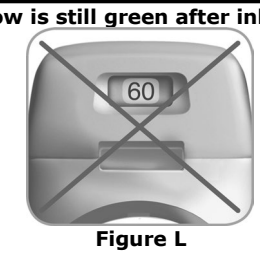


Figure L

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 M), to prevent contamination of the inhaler with dust or other materials. You should discard your inhaler if you lose the cap.

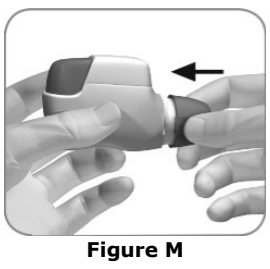


Figure M

Additional information
<u>What should you do if you accidently prepare a dose?</u>
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.

<u>How does the dose indicator work?</u>

- The dose indicator shows the total number of doses left in the inhaler (Figure N).
- On first use, every inhaler contains at least 60 doses, or at least 30 doses, depending on the pack size.
- 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).



Figure N

<u>When should you get a new inhaler?</u>
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 N), or
- If your inhaler is empty (Figure O).

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



Figure O

<u>How do you know that your inhaler is empty?</u>
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 O). 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.

<u>How should you clean the inhaler?</u>
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.