

## **A. PACKAGE LEAFLET**

## **Package leaflet: Information for the user**

### **Glycopyrronium Biogaran 44 microgram, inhalatiepoeder in harde capsule (glycopyrronium)**

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

#### **1. What <Invented name> is and what it is used for**

##### **What <Invented name> is**

This medicine contains an active substance called glycopyrronium bromide. This belongs to a group of medicines called bronchodilators.

##### **What <Invented name> is used for**

This medicine is used to make breathing easier for adult patients who have breathing difficulties due to a lung disease called chronic obstructive pulmonary disease (COPD).

In COPD the muscles around the airways tighten. This makes breathing difficult. This medicine blocks the tightening of these muscles in the lungs, making it easier for air to get in and out of the lungs.

If you use this medicine once a day, it will help to reduce the effects of COPD on your everyday life.

#### **2. What you need to know before you use <Invented name>**

##### **Do not use <Invented name>**

- if you are allergic to glycopyrronium bromide or any of the other ingredients of this medicine (listed in section 6).

##### **Warnings and precautions**

Talk to your doctor before using <Invented name> , if any of the following applies to you:

- you have kidney problems.
- you have an eye problem called narrow-angle glaucoma.
- you have difficulty passing urine.

**During treatment with <Invented name>** , stop taking this medicine and tell your doctor immediately:

- if you experience tightness of the chest, coughing, wheezing or breathlessness immediately after using <Invented name> (signs of bronchospasm).
- if you experience difficulties in breathing or swallowing, swelling of the tongue, lips or face, skin rash, itching and hives (signs of allergic reaction).
- if you experience eye pain or discomfort, temporary blurring of vision, visual halos or coloured images in association with red eyes. These may be signs of an acute attack of narrow-angle glaucoma.

<Invented name> is used as a maintenance treatment for your COPD. Do not use this medicine to treat a sudden attack of breathlessness or wheezing.

### **Children and adolescents**

Do not give this medicine to children or adolescents below the age of 18 years.

### **Other medicines and <Invented name>**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines similar to <Invented name> used for your lung disease, such as ipratropium, oxitropium or tiotropium (so called anticholinergics).

No specific side effects have been reported when <Invented name> has been used together with other medicines used to treat COPD such as reliever inhalers (e.g. salbutamol), methylxanthines (e.g. theophylline) and/or oral and inhaled steroids (e.g. prednisolone).

### **Pregnancy, breast-feeding and fertility**

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.

There are no data from the use of this medicine in pregnant women and it is not known whether the active substance of this medicine passes into human milk.

### **Driving and using machines**

It is unlikely that this medicine will affect your ability to drive and use machines.

### **<Invented name> contains lactose**

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

## **3. How to use <Invented name>**

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

### **How much <Invented name> to use**

The usual dose is to inhale the content of one capsule each day.

You only need to inhale once a day because the effect of this medicine lasts for 24 hours. Do not use more than your doctor tells you to use.

### **Elderly people**

You can use this medicine if you are aged 75 years and over at the same dose as for other adults.

### **When to inhale <Invented name>**

Use this medicine at the same time each day. This will also help you to remember to use it. You can inhale this medicine any time before or after food or drink.

**How to inhale <Invented name>**

- In this pack, you can find an inhaler and capsules (in blisters) that contain the medicine as inhalation powder. Only use the capsules with the inhaler provided in this pack. The capsules should remain in the blister until you need to use them.
- Do not push the capsule through the foil.
- When you start a new pack, use the inhaler that is supplied in the pack or, in case of reuse the inhaler, it should be disposed after 90 uses, counting from the first use of the inhaler.
- Do not swallow the capsules.
- Please read the instructions at the end of this leaflet for more information on how to use the inhaler.

**If you use more <Invented name> than you should**

If you have inhaled too much of this medicine or if someone else accidentally uses your capsules, you must immediately either tell your doctor or go to the nearest emergency unit. Show the pack of <Invented name> . Medical attention may be needed.

**If you forget to use <Invented name>**

If you forget to inhale a dose, take one as soon as possible. However, do not take two doses on the same day. Then take the next dose as usual.

**How long to continue your treatment with <Invented name>**

- Keep using this medicine for as long as your doctor tells you.
- COPD is a long-term disease and you should use this medicine every day and not only when you have breathing problems or other symptoms of COPD.

If you have questions about how long to continue your treatment with this medicine, talk to your doctor or pharmacist.

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.

**Some side effects may be serious but are uncommon**

*(may affect up to 1 in 100 people)*

- Irregular heart beat
- High level of blood sugar (hyperglycaemia: typical symptoms include excessive thirst or hunger and frequent urination)
- Rash, itching, hives, difficulty breathing or swallowing, dizziness (possible signs of allergic reaction)
- Swelling mainly of the tongue, lips, face or throat (possible signs of angioedema) If you get any of these side effects, tell your doctor immediately.

**Some side effects may be serious, but the frequency of these side effects is not known**

*(frequency cannot be estimated from the available data)*

- Difficulty breathing with wheezing or coughing (signs of paradoxical bronchospasm)

**Some side effects are common**

*(may affect up to 1 in 10 people)*

- Dry mouth
- Difficulty sleeping
- Runny or stuffy nose, sneezing, sore throat
- Diarrhoea or stomach ache
- Musculoskeletal pain

**Some side effects are uncommon**

*(may affect up to 1 in 100 people)*

- Difficulty and pain when passing urine
- Painful and frequent urination
- Palpitations
- Rash
- Numbness
- Cough with sputum
- Dental caries
- Feeling of pressure or pain in the cheeks and forehead
- Nose bleeds
- Pain in arms or legs
- Pain in muscles, bones or joints of the chest
- Stomach discomfort after meals
- Throat irritation
- Tiredness
- Weakness
- Itching
- Voice alteration (hoarseness)
- Nausea
- Vomiting

Some elderly patients above 75 years of age experienced headache (frequency common) and urinary tract infection (frequency common).

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store <Invented name>**

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 carton and blister after “EXP”. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store the capsules in the original blister in order to protect from moisture. Do not remove from the blister until immediately before use.

The inhaler from each pack or reused inhaler, it should be disposed after 90 uses, counting from the first use of the inhaler.

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

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 <Invented name> contains**

- The active substance is glycopyrronium bromide. Each capsule contains 63 micrograms of glycopyrronium bromide (equivalent to 50 micrograms glycopyrronium). The delivered dose (the dose that leaves the mouthpiece of the inhaler) is equivalent to 44 micrograms of glycopyrronium.
- The other ingredients of the inhalation powder are lactose monohydrate and magnesium stearate.

### **What <Invented name> looks like and contents of the pack**

<Invented name> 44 micrograms inhalation powder, hard capsules with an orange transparent cap and a colourless transparent body containing white or almost white powder

Each pack may contain a device called an inhaler, together with capsules in its package.

The following pack sizes are available:

Packs containing 10 x 1, 30 x 1, 60 x 1, 90 x 1 hard capsules in peelable perforated unit-dose blister, together with one inhaler.

Packs containing 10 x 1, 30 x 1, 60 x 1 hard capsules in peelable perforated unit-dose blister.

Not all pack sizes may be marketed.

## **Marketing Authorisation Holder and Manufacturer**

### **Marketing Authorisation Holder**

Biogaran  
15 Boulevard Charles De Gaulle  
92700 Colombes  
Frankrijk

### **Manufacturer**

Laboratorios LICONSA S.A.  
Avenida Miralcampo 7, Polígono Industrial Miralcampo  
19200 Azuqueca de Henares, Guadalajara  
Spanje

**In het register ingeschreven onder: RVG 131859**

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Nederland	Glycopyrronium Biogaran 44 microgram, inhalatiepoeder in harde capsule
Frankrijk	GLYCOPYRRONIUM BIOGARAN 44 microgrammes, poudre pour inhalation en gélule

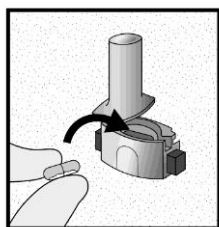
**Deze bijsluiter is voor het laatst goedgekeurd in maart 2025.**

### **Other sources of information**

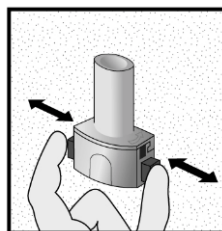
Detailed information on this medicine is available on the web site of: {name of Member State/Agency}

## Instructions for use of the inhaler

Please read the full **Instructions for Use** before using the <Invented name>



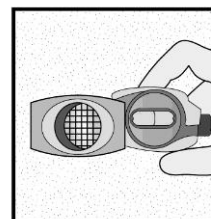
**Insert**



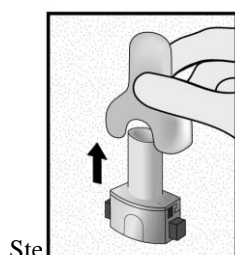
**Pierce and release**



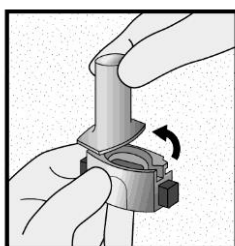
**Inhale deeply**



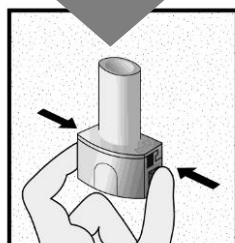
**Check capsule is empty**



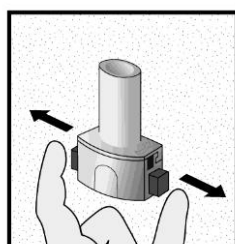
Step 1a:  
**Pull off cap**



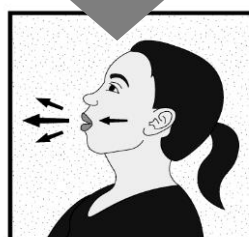
Step 1b:  
**Open inhaler**



Step 2a:  
**Pierce capsule once**  
Hold the inhaler upright. Pierce capsule by firmly pressing both side buttons at the same time. You should hear a noise as the capsule is pierced. Only pierce the capsule once.



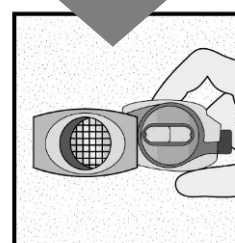
Step 2b:  
**Release side buttons**



Step 3a:  
**Breathe out fully**  
Do not blow into the inhaler.



Step 3b:  
**Inhale medicine deeply**  
Hold the inhaler as shown in the picture. Place the mouthpiece in your mouth and close your lips firmly around it. Do not press the side buttons.



**Check capsule is empty**  
Open the inhaler to see if any powder is left in the capsule.

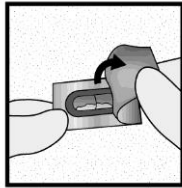
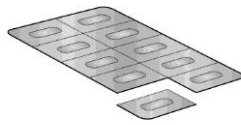
If there is powder left in the capsule:

- Close the inhaler.
- Repeat steps 3a to 3c.

### **Powder remaining**



**Empty**



Step 1c:

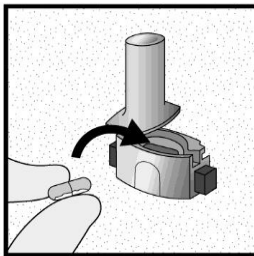
**Remove capsule**

Separate one of the blisters from the blister card.

Peel open the blister and remove the capsule.

Do not push the capsule through the foil.

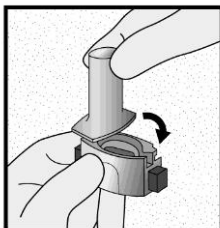
Do not swallow the capsule.



Step 1d:

**Insert capsule**

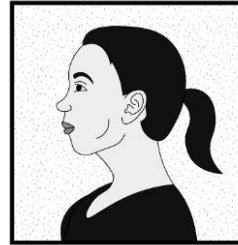
Never place a capsule directly into the mouthpiece.



Step 1e:

**Close inhaler**

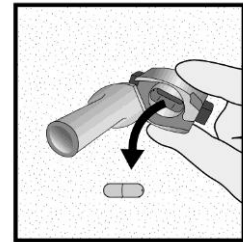
Breathe in quickly and as deeply as you can. During inhalation you will hear a whirring noise. You may taste the medicine as you inhale.



Step 3c:

**Hold breath**

Hold your breath for up to 5 seconds.



**Remove empty capsule**

Put the empty capsule in your household waste. Close the inhaler and replace the cap.

**Important Information**

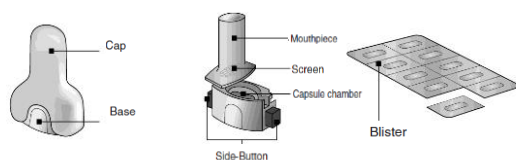
- Glycopyrronium capsules must always be stored in the blister card and only removed immediately before use.
- In case of blister, do not push the capsule through the foil to remove it from the blister.
- Do not swallow the capsule.
- Do not use the Glycopyrronium capsules with any other inhaler.
- Do not use the Glycopyrronium inhaler to take any other capsule medicine.
- Never place the capsule into your mouth or the mouthpiece of the inhaler.
- Do not press the side buttons more than once.
- Do not blow into the mouthpiece.
- Do not press the side buttons while inhaling through the mouthpiece.
- Do not handle capsules with wet hands.



			<ul style="list-style-type: none"><li>• Never wash your inhaler with water.</li></ul>
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Your Glycopyrronium Inhaler pack may contain:

- One Glycopyrronium inhaler
- One or more blister cards, each containing Glycopyrronium capsules to be used in the inhaler



Inhaler

Inhaler base

Blister Card

## Frequently Asked Questions

### Why didn't the inhaler make a noise when I inhaled?

The capsule may be stuck in the capsule chamber. If this happens, carefully loosen the capsule by tapping the base of the inhaler. Inhale the medicine again by repeating steps 3a to 3c.

### What should I do if there is powder left inside the capsule?

You have not received enough of your medicine. Close the inhaler and repeat steps 3a to 3c.

### I coughed after inhaling – does this matter?

This may happen. As long as the capsule is empty you have received enough of your medicine.

### I felt small pieces of the capsule on my tongue – does this matter?

This can happen. It is not harmful. The chances of the capsule breaking into small pieces will be increased if the capsule is pierced more than once.

## Cleaning the inhaler

Wipe the mouthpiece inside and outside with a clean, dry, lint-free cloth to remove any powder residue. Keep the inhaler dry. Never wash your inhaler with water.

## Disposing of the inhaler after use

The inhaler from each pack or reused inhaler, it should be disposed after 90 uses, counting from the first use of the inhaler.

Ask your pharmacist how to dispose of medicines and inhalers that are no longer required.