

## Package leaflet: Information for the user

### Tiotropium Elpen 10 microgram inhalatiepoeder, voorverdeeld tiotropium

**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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

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

#### **1. What <Product Name> is and what it is used for**

<PRODUCT NAME> helps people who have chronic obstructive pulmonary disease (COPD) to breathe more easily. COPD is a chronic lung disease that causes shortness of breath and coughing. The term COPD is associated with the conditions chronic bronchitis and emphysema. As COPD is a chronic disease you should take <PRODUCT NAME> every day and not only when you have breathing problems or other symptoms of COPD.

<PRODUCT NAME> is a long-acting bronchodilator that helps to open your airways and makes it easier to get air in and out of the lungs. Regular use of <PRODUCT NAME> can also 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. It also helps you to be active longer. Daily use of <PRODUCT NAME> will also help to prevent sudden, short-term worsening of your COPD symptoms which may last for several days.

The effect of this medicine lasts for 24 hours, so you only need to use it once a day. For correct dosing of <PRODUCT NAME> please see section 3. How to use <PRODUCT NAME> and the instructions for use are provided at the end of the leaflet.

#### **2. What you need to know before you use <Product Name>**

##### **Do not use <PRODUCT NAME>**

- if you are allergic (hypersensitive) to tiotropium, its active ingredient, or to any other ingredients of this medicine (listed in section 6).
- if you are allergic (hypersensitive) to atropine or substances related to it, e.g. ipratropium or oxitropium.

## **Warnings and precautions**

### **Talk to your doctor or pharmacist before using <Product Name>**

- Talk to your doctor if you suffer from narrow angle glaucoma, prostate problems or have difficulty passing urine.
- If you have problems with your kidneys, please consult your doctor.
- <PRODUCT NAME> is indicated for maintenance treatment of your chronic obstructive pulmonary disease, it should not be used to treat a sudden attack of breathlessness or wheezing.
- Immediate allergic reactions such as rash, swelling, itching, wheezing or breathlessness may occur after administration of <PRODUCT NAME>. If this occurs, please consult your doctor immediately.
- Inhaled medicines such as <PRODUCT NAME> may cause tightness of the chest, coughing, wheezing or breathlessness immediately after inhalation. If this occurs, please consult your doctor immediately.
- Take care not to let the inhalation powder enter your eye as this may result in precipitation or worsening of narrow-angle glaucoma, which is a disease of the eyes. Eye pain or discomfort, blurred vision, seeing halos around lights or coloured images in association with red eyes may be signs of an acute attack of narrow-angle glaucoma. Eye symptoms may be accompanied by headache, nausea or vomiting. You should stop using tiotropium bromide and immediately consult your doctor, preferably an eye specialist, when signs and symptoms of narrow-angle glaucoma appear.
- Dry mouth, which has been observed with anti-cholinergic treatment, may in the long term be associated with dental caries. Therefore, please remember to pay attention to oral hygiene.
- In case you have suffered from a myocardial infarction during the last 6 months or from any unstable or life threatening irregular heart beat or severe heart failure within the past year, please, inform your doctor. This is important to decide if <Product Name> is the right medicine for you to take.
- Do not use <PRODUCT NAME> more frequently than once daily.

### **Children and adolescents**

<Product Name> is not recommended for children and adolescents under 18 years.

### **Other medicines and <Product Name>**

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including medicines available without prescription.

Please tell your doctor or pharmacist if you are using/have used similar medicines for your lung disease, such as ipratropium or oxitropium.

No specific side effects have been reported when tiotropium has been used together with other products 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 and breast-feeding**

If you are pregnant or breast-feeding or think you may be pregnant, or you are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. You should not use this medicine unless specifically recommended by your doctor.

### **Driving and using machines**

The occurrence of dizziness, blurred vision, or headache may influence the ability to drive and use machinery.

**<Product Name> contains lactose monohydrate**

Each unit dose strip contains 11.86 mg of lactose (as monohydrate). If you have been told by your doctor that you have an intolerance to some sugars, or an allergy to milk proteins (which may be contained in small amounts in the ingredient lactose monohydrate), contact your doctor before taking this medicinal product.

**3. How to use <Product 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.

The recommended dose is to inhale the content of 1 strip once a day. Each unit dose strip contains 16 micrograms of tiotropium bromide monohydrate which correspond to 13 micrograms of tiotropium and the dose delivered through the Elpenhaler is 10 micrograms of tiotropium. Do not use more than the recommended dose.

<Product Name> is not recommended for children and adolescents under 18 years.

You should try to use the unit dose strips at the same time every day. This is important because <Product Name> is effective over 24 hours.

The strips are only for inhalation and not for oral intake.  
Do not swallow the content of strips.

The Elpenhaler device, which you should use with the <Product Name> strips, allows you to breathe in the powder.

Make sure that you have an Elpenhaler and that you can use it properly. The instructions for use of the Elpenhaler are provided at the end of this leaflet.

Keep the product inside the aluminum pouch to protect from moisture and only remove immediately before first use.

Make sure that you do not exhale on the mouthpiece of the Elpenhaler.

If you have any problems using the Elpenhaler, ask your doctor, nurse or pharmacist to show you how it works.

You should clean your Elpenhaler after each use. Cleaning instructions for the Elpenhaler are provided at the end of this leaflet.

When taking <Product Name> take care not to let any of the powder enter your eyes. If any powder does get into your eyes you may get blurred vision, eye pain and/or red eyes, you should wash your eyes in warm water immediately. Then talk to your doctor immediately for further advice.

If you feel that your breathing is worsening, you should tell your doctor as soon as possible.

**If you use more <Product Name> than you should**

If you inhale from more than 1 strip of <PRODUCT NAME> in a day, you should talk to your doctor immediately. You may be at a higher risk of experiencing a side effect such as dry mouth, constipation, difficulties passing urine, increased heart beat, or blurred vision.

**If you forget to use <Product Name>**

If you forget to take a dose, take one as soon as you remember but do not take two doses at the same time or on the same day. Then take your next dose as usual.

**If you stop using <Product Name>**

Before you stop using <PRODUCT NAME> you should talk to your doctor or your pharmacist. If you stop using <PRODUCT NAME> the signs and symptoms of COPD may worsen.

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

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The side effects described below have been experienced by people taking this medicine and they are listed according to frequency as either common, uncommon, rare or not known.

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

- dry mouth: this is usually mild

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

- dizziness
- headache
- taste disorders
- blurred vision
- irregular heart beat (atrial fibrillation)
- inflammation of the throat (pharyngitis)
- hoarseness (dysphonia)
- cough
- heart burn (gastrooesophageal reflux disease)
- constipation
- fungal infections of the oral cavity and throat (oropharyngeal candidiasis)
- rash
- difficulties passing urine (urinary retention)
- painful urination (dysuria)

**Rare (may affect up to 1 in 1,000 people):**

- difficulty in sleeping (insomnia)
- seeing halos around lights or coloured images in association with red eyes (glaucoma)
- increase of the measured eye pressure
- irregular heart beat (supraventricular tachycardia)
- faster heart beat (tachycardia)
- feeling your heart beat (palpitations)
- tightness of the chest, associated with coughing, wheezing or breathlessness immediately after inhalation (bronchospasm)
- nosebleed (epistaxis)
- inflammation of the larynx (laryngitis)
- inflammation of the sinuses (sinusitis)
- blockage of intestines or absence of bowel movements (intestinal obstruction including ileus paralytic)
- inflammation of the gums (gingivitis)

- inflammation of the tongue (glossitis)
- difficulties swallowing (dysphagia)
- inflammation of the mouth (stomatitis)
- feeling sick (nausea)
- hypersensitivity, including immediate reactions
- serious allergic reaction which causes swelling of the face or throat (angioedema)
- nettle rash (urticaria)
- itching (pruritus)
- infections of the urinary tract

**Not known (frequency cannot be estimated from the available data):**

- depletion of body water (dehydration)
- dental caries
- severe allergic reaction (anaphylactic reaction)
- infections or ulcerations of the skin
- dryness of the skin
- swelling of joints

Serious side effects include allergic reactions which cause swelling of the face or throat (angioedema) or other hypersensitivity reactions (such as sudden reduction of your blood pressure or dizziness) may occur individually or as part of severe allergic reaction (anaphylactic reaction) after administration of <Product Name>. In addition, in common with all inhaled medicines, some patients may experience an unexpected tightness of the chest, coughing, wheezing or breathlessness immediately after inhalation (bronchospasm). If any of these occur, please consult your doctor immediately.

**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 <Product 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, the aluminum pouch, the label and the unit dose strips. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.

Store in the original package in order to protect from moisture. After first opening of the aluminum pouch, use within 60 days, stored below 25°C.

Write the date of first opening of the pouch on the sticker provided on the pouch. Place the sticker on the bottom of the device. Discard the aluminum pouch and the desiccant sachet.

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 <Product Name> contains**

The active substance is tiotropium. Each unit dose strip contains 16 micrograms of tiotropium bromide monohydrate which correspond to 13 micrograms of tiotropium. During inhalation, 10 micrograms of tiotropium are delivered through the mouthpiece of the Elpenhaler.

The other ingredient is lactose monohydrate (which may contain small amounts of milk proteins).

### **What <Product Name> looks like and contents of the pack**

1 white plastic inhalation device Elpenhaler which contains 30 unit dose strips, is packed in an aluminum pouch with a desiccant sachet. The aluminum pouch is packed in a carton box together with the patient information leaflet. Pack of 30 doses.

2 white plastic inhalation devices Elpenhaler each containing 30 unit dose strips, are packed in separate aluminum pouches, with a desiccant sachet. The 2 aluminum pouches are packed in a carton box together with the patient information leaflet. Pack of 60 doses.

3 white plastic inhalation devices Elpenhaler each containing 30 unit dose strips, are packed in separate aluminum pouches, with a desiccant sachet. The 3 aluminum pouches are packed in a carton box together with the patient information leaflet. Pack of 90 doses.

Not all pack sizes may be marketed.

Once you have opened the aluminum pouch, throw the pouch and the desiccant sachet away – do not eat or inhale it.

The unit dose strips placed inside the Elpenhaler should be only used with this specific device before the expiry date stated on the label.

### **Marketing Authorisation Holder and Manufacturer**

ELPEN Pharmaceutical Co. Inc.  
95 Marathonos Ave.  
Pikermi Attica, 19009  
Griekenland

### **Marketing Authorisation Number**

RVG 126836

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

Cyprus:	Tioresp 10 mcg κόνις για εισπνοή σε δόσεις
Duitsland:	Tiotropium ELPEN 10 Mikrogramm einzeldosiertes Pulver zur Inhalation
Griekenland:	Tioresp 10 mcg κόνις για εισπνοή σε δόσεις
Nederland:	Tiotropium Elpen 10 microgram inhalatiepoeder, voorverdeeld
Italië:	Tiotropio Elpen

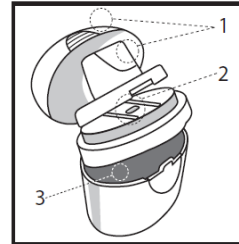
**This leaflet was last revised in oktober 2021.**

## INSTRUCTIONS FOR USE OF THE ELPENHALER®:

Elpenhaler® is a device for the intake of powder for inhalation in doses.  
Each dose is stored in the blister of a specially designed unit dose blister strip.

Elpenhaler® device is comprised of 3 parts:

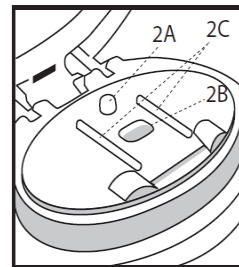
- The mouthpiece and its cap (1).
- The surface (2) on which the blister strip is placed (drug supporting surface).
- The storage case (3) which houses the blister strips.



The three parts are connected to each other and can be opened separately.

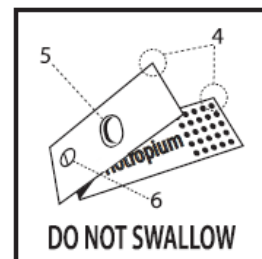
The drug supporting surface contains:

- An attachment point (2A) where the blister strip is attached.
- A cavity (2B) which accommodates the blister of the strip.
- Two strip guides (2C) which firmly secure the blister strip in the correct position on the drug supporting surface.



The blister strip consists of:

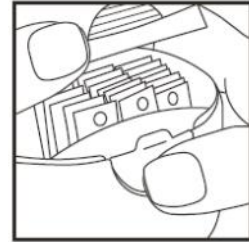
- Two aluminum sheets (4).
- A blister (5), containing the medicine.
- A hole (6).



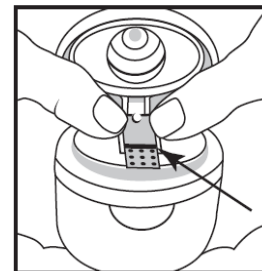
## USE OF THE ELPENHALER®

## A. Preparing the device

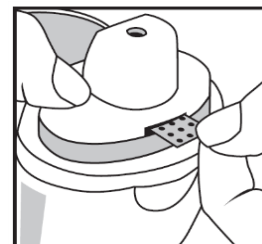
- Open the storage case by pressing as in the figure, take a strip and close the storage case again.



- Uncover the mouthpiece completely by applying light pressure on the striped area.
- Unlock and push the mouthpiece backwards so as to reveal the drug supporting surface.
- Hold the blister strip with its shiny surface upwards, so as to see the blue line, as shown by the arrow in the figure. The labeled surface of the strip should face downwards.
- Place the hole of the strip on the attachment point of the drug supporting surface. By applying light pressure make sure that the strip is securely attached on the attachment point.
- The blister of the strip will fit in the cavity of the drug supporting surface and the guides will secure the strip in the correct position.



- Close the mouthpiece, pull away horizontally the embossed protruding end of the strip so as to be detached, and discard it.
- The dose is now ready to be inhaled.

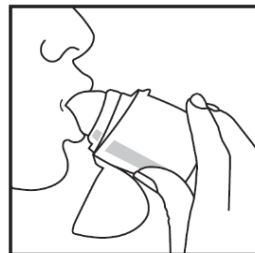


## B. Inhalation of the dose

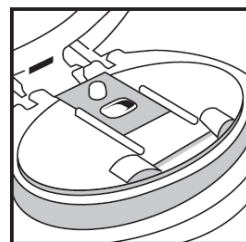


Hold the device away from your mouth. Exhale completely. Be careful not to exhale on the mouthpiece of the device. Bring Elpenhaler® to your mouth and place your lips tightly around the mouthpiece.

- Breathe in slowly and deeply through your mouth (and not through your nose) until your lungs are full.
- Hold in your breath approximately 5 seconds or as long as you comfortably can and at the same time remove the device from your mouth.
- Exhale and continue to breathe normally.



- Open the mouthpiece.
- You will notice that you have inhaled all the powder and that the blister of the strip is empty.
- Remove the empty strip, discard it, and proceed to step C.



### **C. Cleaning the device**

Following each use, wipe the mouthpiece and the drug supporting surface with a dry cloth or dry paper tissue. Do not use water to clean the device.

Close the mouthpiece and its cap.