

## Package leaflet: Information for the user

### Tiotropium ProPharma Group, 18 microgram, inhalation powder, hard capsule 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 Tiotropium ProPharma Group is and what it is used for
2. What you need to know before you use Tiotropium ProPharma Group
3. How to use Tiotropium ProPharma Group
4. Possible side effects
5. How to store Tiotropium ProPharma Group
6. Contents of the pack and other information

#### 1. What Tiotropium ProPharma Group is and what it is used for

Tiotropium ProPharma Group 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 Tiotropium ProPharma Group every day and not only when you have breathing problems or other symptoms of COPD.

Tiotropium ProPharma Group 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 Tiotropium ProPharma Group can also help you when you have on-going shortness of breath related to your disease and will help you to minimize the effects of the disease on your everyday life. It also helps you to be active longer. Daily use of Tiotropium ProPharma Group 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 Tiotropium ProPharma Group please see section 3. *How to use Tiotropium ProPharma Group* and the instructions for use provided on the other side of the leaflet.

#### 2. What you need to know before you use Tiotropium ProPharma Group

##### Do not use Tiotropium ProPharma Group

- 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 Tiotropium ProPharma Group:

- 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.
- Tiotropium ProPharma Group 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 Tiotropium ProPharma Group. If this occurs, please consult your doctor immediately.
- Inhaled medicines such as Tiotropium ProPharma Group 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 ProPharma Group 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 heartbeat or severe heart failure within the past year, please inform your doctor. This is important to decide if Tiotropium ProPharma Group is the right medicine for you to take.
- Do not use Tiotropium ProPharma Group more frequently than once daily.

### **Children and adolescents**

Tiotropium ProPharma Group is not recommended for children and adolescents under 18 years.

### **Other medicines and Tiotropium ProPharma Group**

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 ProPharma Group 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, 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 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.

### **Tiotropium ProPharma Group 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 Tiotropium ProPharma Group

- 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 contents of 1 capsule (18 micrograms of tiotropium) once a day. Do not use more than the recommended dose.
- Tiotropium ProPharma Group is not recommended for children and adolescents under 18 years.
- You should try to use the capsule at the same time every day. This is important because Tiotropium ProPharma Group is effective over 24 hours.
- The capsules are only for inhalation and not for oral intake. Do not swallow the capsules.
- The Tiotropium ProPharma Group Dry Powder Inhaler, which you should put the Tiotropium ProPharma Group capsule into, makes holes in the capsule and allows you to breathe in the powder.
- The capsules must only be inhaled using the inhaler provided with the Tiotropium ProPharma Group capsules. Do not use any other inhalers to administer Tiotropium ProPharma Group capsules.
- Make sure that you have a Tiotropium ProPharma Group inhaler and that you can use it properly. The instructions for use of the Dry Powder Inhaler are provided at the end of this leaflet. If you have any problems using the Dry Powder Inhaler, ask your doctor, nurse or pharmacist to show you how it works.
- When taking Tiotropium ProPharma Group, 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 Tiotropium ProPharma Group than you should**

If you inhale from more than 1 capsule of Tiotropium ProPharma Group 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 heartbeat, or blurred vision.

#### **If you forget to use Tiotropium ProPharma Group**

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 Tiotropium ProPharma Group**

Before you stop using Tiotropium ProPharma Group, you should talk to your doctor or your pharmacist. If you stop using this medication 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.

**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 Tiotropium ProPharma Group. 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.

**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 heartbeat (atrial fibrillation)
- inflammation of the throat (pharyngitis)
- Hoarseness (dysphonia)
- Cough
- Heart burn (gastroesophageal reflux disease)
- Constipation
- Fungal infections of the oral cavity and throat (oropharyngeal candidiasis)
- Rash
- Difficulty 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 heartbeat (supraventricular tachycardia)
- Faster heartbeat (tachycardia)
- Feeling your heartbeat (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

**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 HPRÁ Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects, you can help provide more information on the safety of this medicine.

## **5. How to store Tiotropium ProPharma Group**

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 the blister foil. The expiry date refers to the last day of that month.

Use the capsule directly after opening of the blister pocket. Use the device which comes with the pack. In case you have a supplemental blister pack containing Tiotropium ProPharma Group capsules only, you can use the device already available to you. When you have used the device for 6 months, it needs to be replaced by a new device.

Do not store above 30°C.

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 Tiotropium ProPharma Group contains**

The active substance is tiotropium. Each capsule contains 18 microgram tiotropium (as tiotropium bromide). During inhalation, 10 micrograms of tiotropium are delivered from the mouthpiece of the inhaler. The product consists also of:

- capsule content: lactose (see section 2)
- capsule shell: hypromellose
- capsule printing ink: shellac, black iron oxide, propylene glycol, ammonia, potassium hydroxide.

### **What Tiotropium ProPharma Group looks like and contents of the pack**

Tiotropium ProPharma Group inhalation powder, hard capsule is a colourless and transparent hard capsule, with “T10” printed on it, containing a white powder.

This medicine is provided in blisters. The blisters are supplied in a cardboard box, depending on the pack the box will also contain a Dry Powder Inhaler (MRX003-R). The Dry Powder Inhaler has a white body with a red push button.

- Cardboard box containing 30 capsules (3 blisters) with a Dry Powder Inhaler
- Cardboard box containing 60 capsules (6 blisters) with a Dry Powder Inhaler
- Cardboard box containing 90 capsules (9 blisters) with a Dry Powder Inhaler
- Cardboard box containing 30 capsules (3 blisters)
- Cardboard box containing 60 capsules (6 blisters)
- Cardboard box containing 90 capsules (9 blisters)

Not all pack sizes may be marketed.

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

Marketing Authorisation Holder

ProPharma Group, The Netherlands, B.V.  
Schipholweg 73-75  
2316 ZL, Leiden  
The Netherlands

Manufacturer

Helm AG  
Nordkanalstrasse 28, Hammerbrook  
20097, Hamburg  
Germany

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

<b>Country</b>	<b>Product name</b>
Sweden	Tiotropium ProPharma Group, 18 mikrogram, inhalationspulver, hård kapsel
Finland	Tiotropium ProPharma Group, 18 mikrog inhalaatiojauhe, kapseli, kova
Denmark	Tiotropium ProPharma Group
Norway	Tiotropium ProPharma Group
Ireland	Tiotropium ProPharma Group, 18 microgram inhalation powder, hard capsule

**This leaflet was last revised in <{MM/YYYY}> <{month YYYY}>.**

October 2020

**Instructions for Use  
Dry Powder Inhaler (MRX003-R)**

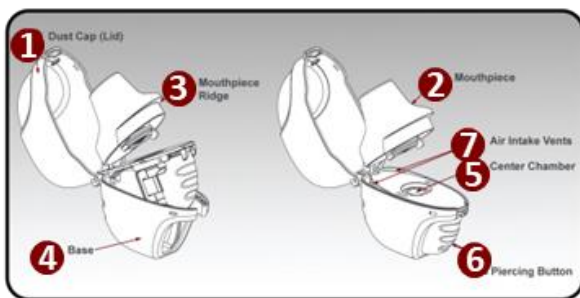
Dear patient,

The Dry Powder Inhaler enables you to inhale the medicine contained in the Tiotropium ProPharma Group capsule that your doctor has prescribed you for your breathing problems.

Remember to carefully follow your doctor’s instructions for using Tiotropium ProPharma Group. The Dry Powder Inhaler is especially designed for Tiotropium ProPharma Group capsules: you must not use it to take any other medication. The capsules must only be inhaled using the Dry Powder Inhaler provided with the Tiotropium ProPharma Group capsules. Do not use any other inhalers to administer Tiotropium ProPharma Group capsules.

Make sure you had sufficient training from a healthcare professional before you use the Dry Powder Inhaler.

Do not use the Dry Powder Inhaler for more than 6 months and do not use the Dry Powder Inhaler beyond the device expiry date.

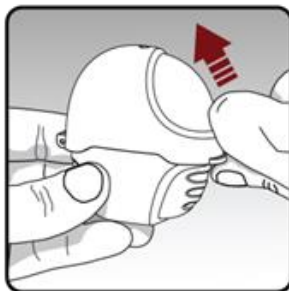


The Dry Powder Inhaler includes:

- 1 Dust cap (lid)
- 2 Mouthpiece
- 3 Mouthpiece ridge
- 4 Base
- 5 Centre chamber
- 6 Piercing Button
- 7 Air intake vents

**Taking your full daily dose of medicine requires 4 main steps**

**Step 1. Opening your Dry Powder Inhaler:**



- Open the dust cap (lid).



- Open the mouthpiece by pulling the mouthpiece up.

## Step 2. Inserting the capsule into your Dry Powder Inhaler:



Remove a capsule from the blister (only immediately before use, see *Blister Handling*) and place the capsule in the centre chamber of your Dry Powder Inhaler. It does not matter which side of the capsule is up or down.



Close the mouthpiece firmly against the grey base until you hear a click. Leave the dust cap (lid) open.

## Step 3. Piercing the capsule:

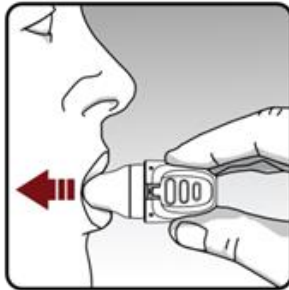


- Hold your Dry Powder Inhaler with the mouthpiece pointed up.
- Press the piercing button once fully in until it stops, then release. This makes holes in the capsule and allows the medication to be released when you breathe in.
- **Do not** push upward on the base while pressing the piercing button. This may cause the device to open, such as for cleaning (see *Cleaning Your Dry Powder Inhaler*).
- Keep your inhaler in an upright position
- **Do not** shake your Dry Powder Inhaler.

## Step 4. Taking your full daily dose (2 inhalations from the same capsule):



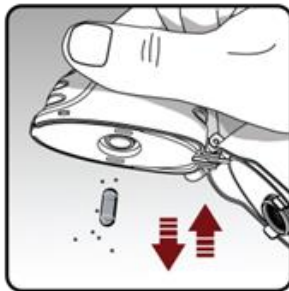
- **Breathe out completely in 1 breath**, emptying your lungs of any air.
- **Important: Do not** breathe into your Dry Powder Inhaler.



With your next breath, take your medicine:

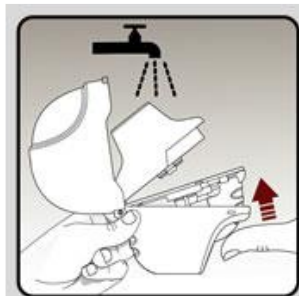
- **Hold your head in an upright position while you are looking straight ahead.**
- Raise your Dry Powder Inhaler to your mouth in a horizontal position. Do not block the air intake vents.
- Close your lips tightly around the mouthpiece.
- Breathe in slowly and deeply until your lungs are full. You should hear and/or feel the capsule vibrate (rattle).
- Hold your breath for a few seconds and, at the same time, take your Dry Powder Inhaler out of your mouth.
- Breathe normally again.
- Repeat step 4, in order to empty the capsule completely.

#### Cleaning your Dry Powder Inhaler:



#### Empty your Dry Powder Inhaler every day

- After taking your daily dose, open the mouthpiece and tip out the used capsule into your trash can.
- Remove any capsule pieces or powder build up by turning your Dry Powder Inhaler upside down and gently, but firmly, tapping it. Then close the mouthpiece and dust cap for storage.



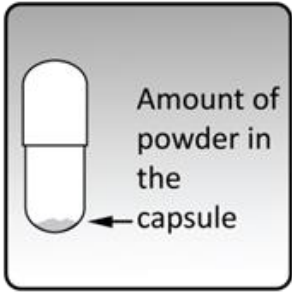


**Clean** the dry powder inhaler monthly.

**It takes 24 hours to air-dry your dry powder inhaler after you clean it**, so clean it right after you have used it and it will be ready for your next dose.

#### Cleaning Steps:

- Open the dust cap and mouthpiece.
- Open the base by pushing the piercing button upwards.
- Look in the centre chamber for capsule pieces or powder build-up. If seen, tap out.
- Rinse your dry powder inhaler with warm water, pressing the button a few times so that the centre chamber and the piercing needle is under the running water. Check that any powder build-up or capsule pieces are removed.

	<ul style="list-style-type: none"> <li>• Dry your dry powder inhaler well by tipping the excess water out on a paper towel. Air-dry afterwards, leaving the dust cap, mouthpiece, and base open by fully spreading it out so that it dries completely. If needed, you may clean the outside of the mouthpiece with a clean damp cloth.</li> </ul>
<p><b>Blister handling:</b></p>	
	<p>Each day, separate only 1 of the blisters from the blister card by tearing along the perforated line.</p>
	<p>Remove the Tiotropium ProPharma Group capsule from the blister:</p> <ul style="list-style-type: none"> <li>• Do not cut the foil or use sharp instruments to take out the capsule from the blister.</li> <li>• Bend 1 of the blister corners with an arrow and separate the aluminium foil layers.</li> <li>• Peel back the printed foil until you see the whole capsule (only immediately before use).</li> <li>• If you have opened more than 1 blister to the air, the extra capsule should not be used and should be thrown away.</li> </ul>
	<ul style="list-style-type: none"> <li>• Each Tiotropium ProPharma Group capsule contains only a small amount of powder. This is 1 full dose.</li> </ul>
<p><b>Helpful Hints</b>  <b>to help ensure that you are properly taking your full dose of your medicine:</b></p> <ul style="list-style-type: none"> <li>• Press the piercing button 1 time; breathe in 2 times; breathe out completely before each of the 2 inhalations</li> <li>• Keep your Dry Powder Inhaler with the mouthpiece pointed up when pressing the piercing button</li> <li>• Do not breathe out into your Dry Powder Inhaler</li> <li>• Keep your Dry Powder Inhaler in a horizontal position and keep your head upright, looking straight ahead, when breathing in.</li> </ul>	

- Check the centre chamber of your Dry Powder Inhaler for capsule pieces or powder build-up. If pieces or powder are seen, tap out before use.
- Clean your Dry Powder Inhaler monthly and dry thoroughly.

**Additional Information**

- There are no special precautions for device disposal.
- Do not use the device if it is visibly damaged or if a capsule remains in the device.

**Legal Manufacturer**

of the Dry Powder Inhaler

Phagentis S.A.  
Via Figino 6  
6917 Barbengo  
Switzerland

**SEP2020**

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