

Package leaflet: Information for the user

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

1. What Tiotropium Clonmel is and what it is used for

Tiotropium Clonmel contains the active substance tiotropium. It 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 Clonmel every day and not only when you have breathing problems or other symptoms of COPD.

Tiotropium Clonmel 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 Clonmel 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 Tiotropium Clonmel will also help to prevent sudden, short-term worsening of your COPD symptoms which may last for several days.

2. What you need to know before you use Tiotropium Clonmel

DO NOT use Tiotropium Clonmel

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

Warnings and precautions

Talk to your doctor or pharmacist before using Tiotropium Clonmel

- 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 Clonmel 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 Clonmel. If this occurs, please consult your doctor immediately.

- Inhaled medicines such as Tiotropium Clonmel 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 Clonmel 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 Clonmel is the right medicine for you to take.
- Do not use this medicine more frequently than once daily.

Children and adolescents

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

Other medicines and Tiotropium Clonmel

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 Clonmel 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 Clonmel 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. Lactose contains small amounts of milk proteins which may cause allergic reactions.

3. How to use Tiotropium Clonmel

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. **You must breathe in 2 times from the same capsule** (see section "Instructions for handling and use" at the end of this leaflet). Do not use more than the recommended dose.

You should try to use the capsule at the same time every day. This is important because Tiotropium Clonmel is effective over 24 hours.

Use in children and adolescents

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

Method of administration

The capsules are only for inhalation and not for oral intake. Do not swallow the capsules.

The capsule should only be removed from the blister immediately before using the inhaler!

The Vertical-Haler, which you should put the Tiotropium Clonmel capsule into, makes holes in the capsule and allows you to breathe in the powder.

Make sure that you have a Vertical-Haler and that you can use it properly. The instructions for use of the Vertical-Haler are provided at the end of this leaflet.

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

If you use more Tiotropium Clonmel than you should

If you inhale from more than 1 capsule of Tiotropium Clonmel 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 Tiotropium Clonmel

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

If you stop using Tiotropium Clonmel

Before you stop using Tiotropium Clonmel, you should talk to your doctor or your pharmacist. If you stop using this medicine 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 using this medicine.

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 Clonmel. In addition, 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.

Other side effects

Common (may affect up to 1 in 10 people)

- dry mouth

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 (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 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)
- allergic reactions (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)
- tooth decay (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 HPRA Pharmacovigilance, Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tiotropium Clonmel

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

Do not store above 30 °C.

Discard the inhaler 90 days after first use.

The capsule should be used directly after opening the blister.

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 Clonmel contains

The active substance is tiotropium.

Each capsule contains 22.5 microgram tiotropium bromide monohydrate equivalent to 18 microgram tiotropium. The delivered dose (the dose that leaves the mouthpiece of the Vertical-Haler device) is 10 microgram tiotropium.

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

The capsule shell contains gelatin (E441), water, macrogol 4000 (E1521), titanium dioxide (E171), yellow iron oxide (E172) and Brilliant Blue (E133).

What Tiotropium Clonmel looks like and contents of the pack

Tiotropium Clonmel is a opaque green capsule with a size of 16 mm x 5.8 mm containing the inhalation powder.

Aluminium / Aluminium push-through blister containing 5 or 10 capsules.

Tiotropium Clonmel is available in the following packs:

- Carton box containing Vertical-Haler device and 10 capsules
- Carton box containing Vertical-Haler device and 15 capsules
- Carton box containing Vertical-Haler device and 30 capsules
- Carton box containing Vertical-Haler device and 60 capsules
- Carton box containing Vertical-Haler device and 90 capsules
- Hospital pack: Carton box containing Vertical-Haler device and 5x30 capsules (bundle pack)

- Carton box containing two Vertical-Haler devices and 60 capsules
- Carton box containing three Vertical-Haler devices and 90 capsules

- Hospital pack: Carton box containing 5x60 capsules (bundle pack)
- Carton box containing 30 capsules
- Carton box containing 60 capsules
- Carton box containing 90 capsules

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer

Pharmadox Healthcare Ltd, KW20A Kordin Industrial Park, Paola PLA 3000, Malta
STADA Arzneimittel AG, Stradastrasse 2-18, 61118 Bad Vilbel, Germany
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland
Centrafarm Services B.V., Van de Reijtstraat 31 E, NL-4814NE, Breda, Netherlands
STADA Arzneimittel GmbH, Muthgasse 36/2, 1190 Wien, Austria

This leaflet was last revised in May 2024.

Instructions for handling and use

Remember to carefully follow your doctor's instructions for using Tiotropium Clonmel. The Vertical-Haler is especially designed for Tiotropium Clonmel. You must not use it to take any other medication. You can use your Vertical-Haler for up to 90 days to take your medication.

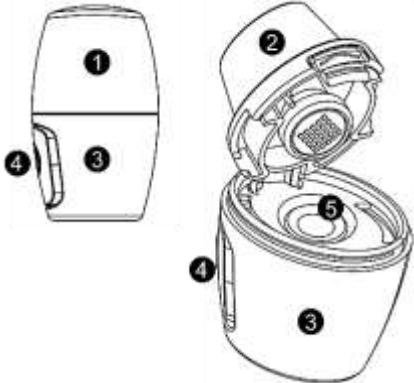
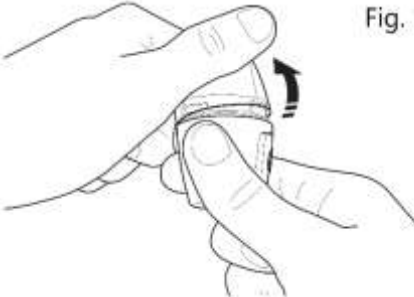
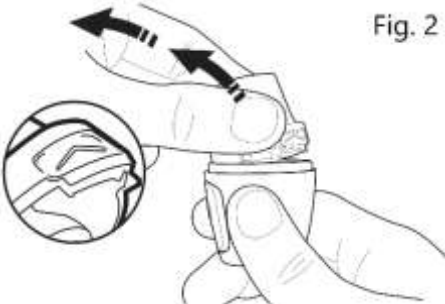
	Vertical-Haler - explanation of different parts 1 Cap 2 Mouthpiece 3 Base 4 Push button 5 Capsule chamber
 Fig. 1	1. Removing the cap Hold the Vertical-Haler and remove the cap upwards from the base to expose mouthpiece as shown (Fig. 1).
 Fig. 2	2. Opening To open the Vertical-Haler, hold it on the base sides. Press the "A" marked area (as shown on enlarged picture) with your fingertip. Open the inhaler by pulling the mouthpiece up away from the base as shown (Fig. 2).

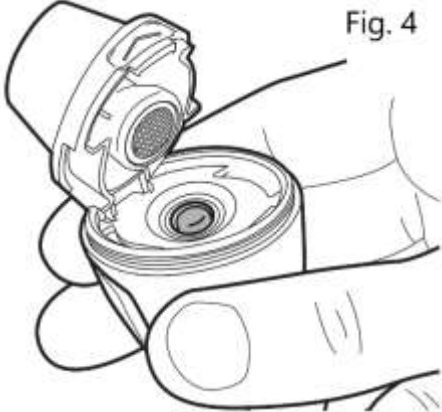
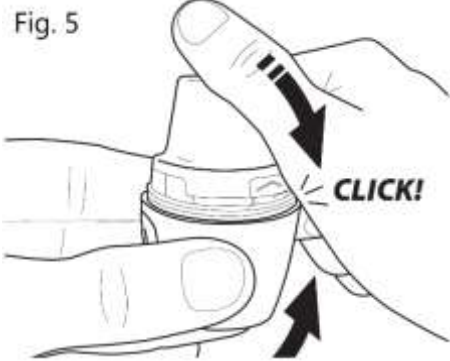
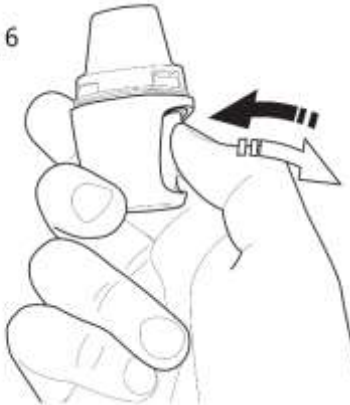
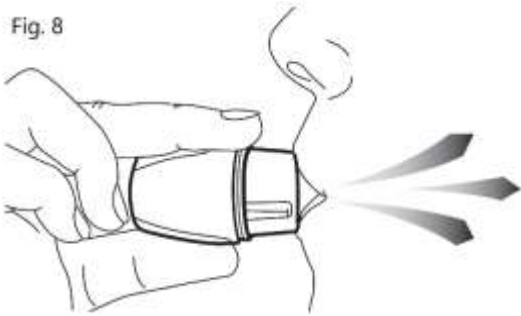
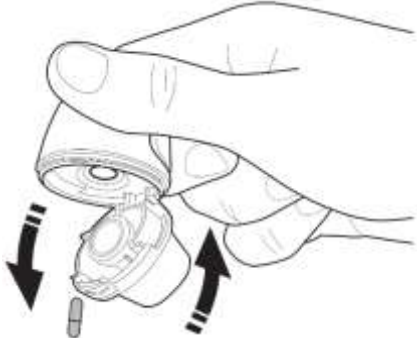
Fig. 3 	3. Inserting the capsule Hold the Vertical-Haler opened upward. Insert the capsule shell inside the capsule chamber (Fig. 3). <u>Please note:</u> Remove the capsule from the blister only <u>immediately before</u> using the inhaler!
Fig. 4 	Make sure that the capsule shell is correctly inserted (Fig. 4).
Fig. 5 	4. Closing the compartment Close the mouthpiece firmly against the base until you will hear a “click” (Fig. 5).
Fig. 6 	5. Piercing the capsule Hold the Vertical-Haler with the mouthpiece upwards. Press the button firmly once full course until it is totally hidden (Fig. 6). Release the button back up. This will pierce the capsule, so you can inhale the medication when you breathe in. Attention: In case you need to repeat Step 5, open the capsule chamber (Fig. 2) to make sure the capsule shell is correctly inserted (Fig. 4).

Fig. 7 	6. Prepare to use Hold the Vertical-Haler away from your mouth and breathe out emptying your lungs of air. (Fig. 7) Do not blow into the Vertical-Haler.
Fig. 8 	7. Inhalation Hold your next breath with the head in upright position, seal your lips around the mouthpiece. Inhale slowly and deeply as possible (Fig. 8). You will hear a vibrating sound of the capsule rotating inside the capsule chamber for dispersion of the drug. Breathe in until your lungs are full; then hold your breath as long as comfortable and at the same time take the Vertical-Haler out of your mouth. Resume normal breathing. Repeat steps 6 and 7 one more time. You must breathe in 2 times from the same capsule.
	Attention: When holding the inhaler during inhalation, make sure not to block the airways located on the sides of the mouthpiece. This can impede the air to flow inside the inhaler, reducing the capsule movement, and drug dispersion. Do not push the mouthpiece down during inhalation. This can block the capsule movement.
	Cleaning your Vertical-Haler After use, open the mouthpiece. Hold the inhaler facing down to remove the capsule from the capsule chamber. Clean the mouthpiece and the capsule chamber with a clean, dry cloth. Alternatively, a soft, clean brush can be used to remove residual powder inside the capsule chamber. Close the mouthpiece and place the cap on. This will keep the dry powder inhaler clean and dry. If needed, the outside of the mouthpiece should be cleaned with a damp cloth.

Please note:

Tiotropium Clonmel capsules contain only a small amount of powder so that the capsule is only partially filled.