

Package leaflet: Information for the user

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

1. What Tiogiva is and what it is used for

Tiogiva contains the active substance tiotropium. Tiotropium helps people who have chronic obstructive pulmonary disease (COPD). 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 Tiogiva every day and not only when you have breathing problems or other symptoms of COPD.

Tiogiva 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 Tiogiva 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 Tiogiva 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 Tiogiva

Do not use Tiogiva

- if you are allergic (hypersensitive) to tiotropium or 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 Tiogiva.

- Talk to your doctor if you suffer from narrow angle glaucoma, prostate problems or have difficulty passing urine.
- If you have any kidney problems please consult your doctor.
- 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.
- Tiogiva 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 Tiogiva. If this occurs, please consult your doctor immediately.

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

Children and adolescents

COPD

Tiogiva is not recommended for children and adolescents under 18 years.

Cystic fibrosis

The safety and efficacy of Tiogiva in children and adolescents has not been established. No data are available.

Other medicines and Tiogiva

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 Tiogiva 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 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.

Tiogiva contains lactose monohydrate

Lactose is a source of glucose and galactose. If you have one of the rare genetic disorders galactosaemia, or glucose-galactose intolerance or congenital lactase deficiency you must talk to your doctor or pharmacist before taking this medicine.

3. How to use Tiogiva

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.

Tiogiva 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 Tiogiva is effective over 24 hours.

The capsules are only for inhalation and not for oral intake. Do not swallow the capsules. Detailed instructions, including pictograms, on how to use the dry powder inhaler are provided at the end of this leaflet.

The dry powder inhaler (MRX003-R), which you should put the Tiogiva capsule into, makes holes in the capsule and allows you to breathe in the powder.

Make sure that you have a dry powder inhaler and that you can use it properly. The instructions for use of the dry powder inhaler are provided in this leaflet.

Make sure that you do not blow into the dry powder inhaler.

You should clean your dry powder inhaler once a month. Cleaning instructions for the dry powder inhaler are provided on the other side of this leaflet.

When taking Tiogiva, 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 Tiogiva than you should

If you inhale from more than 1 capsule of Tiogiva 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 Tiogiva

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

If you stop using Tiogiva

Before you stop using Tiogiva, you should talk to your doctor or your pharmacist. If you stop using this medication the signs and symptoms of COPD may get worse.

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.

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 Tiogiva. 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 heart beat (atrial fibrillation)
- Sore 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 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)
- 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 the Yellow Card Scheme at

www.mhra.gov.co.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 Tiogiva

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 Tiogiva capsules only, you can use the device already available to you. You have to replace the device following the administration of maximal 180 capsules.

Once you have removed your capsule from a particular blister you must continue to remove the capsules for the next 9 days, one capsule a day from the same blister.

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 Tiogiva contains

- The active substance is tiotropium. Each capsule contains 18 microgram tiotropium (as tiotropium bromide). During inhalation, 10 micrograms of tiotropium are delivered to the patient from each capsule from the dry powder inhaler and inhaled into the lungs.
- The other ingredients are lactose monohydrate (capsule content), hypromellose (capsule shell) and capsule printing ink (composed of shellac, black iron oxide, propylene glycol, strong ammonia solution, potassium hydroxide).

What Tiogiva looks like and contents of the pack

Tiogiva 18 microgram hard capsule is a colourless and transparent hard capsule, containing 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.

The dry powder inhaler has a white body with a red push button.

Package sizes:

- 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

Glenmark Pharmaceuticals Europe Limited

Laxmi House, 2B Draycott Avenue
Kenton, Middlesex, HA3 0BU
United Kingdom

Manufacturer

Helm Pharmaceuticals GmbH
Nordkanalstrasse 28
20097 Hamburg
Germany

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Instructions For Use

Dry Powder Inhaler (MRX003-R)

Dear patient,

The MRX003-R dry powder inhaler enables you to inhale the medicine contained in the Tiogiva capsule that your doctor has prescribed you for your breathing problems.

The MRX003-R dry powder inhaler is especially designed for Tiogiva capsules: you must not use it to take any other medication. The capsules must only be inhaled using this inhaler. Do not use any other inhalers to administer Tiogiva capsules.

The dry powder inhaler should only be used with the blister of capsules provided.

- **Do not** use your dry powder inhaler to take any other medicine.
- **Do not** use the dry powder inhaler for more than 180 days.
- **Do not** use the dry powder inhaler beyond the device expiry date.

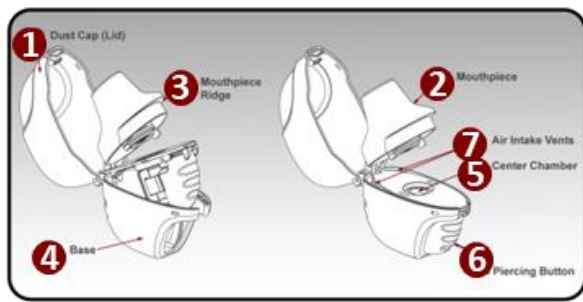
Dispose of the dry powder inhaler once all accompanying capsules have been used or, when used in combination with supplemental blister packs containing tiotropium capsules, dispose of the dry powder inhaler after a period of 180 days.

First read the Patient Information, then read these Instructions for Use before you start to use your dry powder inhaler and each time you refill your prescription. There may be new information.

Becoming familiar with your dry powder inhaler and Tiogiva capsules:

If this is your first time using an inhaler of any kind, make sure you have had sufficient training from your healthcare professional before you use the dry powder inhaler.

Your dry powder inhaler comes with capsules in blister packaging. Use, where applicable, the new dry powder inhaler provided with your medicine. Each dry powder inhaler should be replaced after a maximum of 180 days.



The parts of your dry powder inhaler include: (see Figure A)

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

Figure A

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

Step 1: Opening your dry powder inhaler

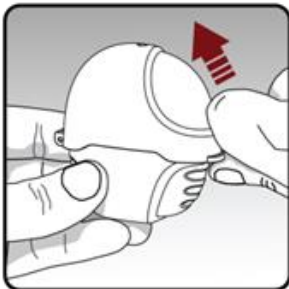


Figure B

After removing your dry powder inhaler from the pouch:

- Open the dust cap (lid) by lifting the dust cap (lid). (see Figure B)

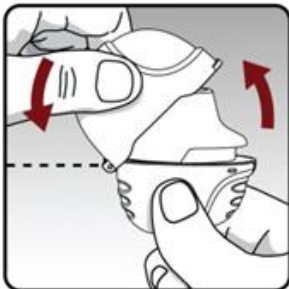


Figure C

- Pull the dust cap (lid) upwards away from the base to expose the mouthpiece. (see Figure C)



Figure D

- Open the mouthpiece by pulling the mouthpiece ridge up and away from the base so the centre chamber is showing. (see Figure D)

Step 2: Inserting the capsule into your dry powder inhaler



Figure E

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 (See Figure E)



Figure F

Close the mouthpiece firmly against the grey base until you hear a click. (see Figure F)

Leave the dust cap (lid) open.

Step 3: Piercing the capsule:



Figure G

- Hold your dry powder inhaler with the mouthpiece pointed up. (see Figure G)
- Press the piercing button once fully in until it stops, then release. This is how you make holes in the capsule so that you get your medicine when you breathe in.
- **Do not** press the piercing button more than one time.
- **Do not** push upward on the base while pressing the piercing button. This may cause the device to open, such as for cleaning (see Caring for and Storing Your Dry Powder Inhaler).
- **Keep** your inhaler in an upright position.
- **Do not** shake your dry powder inhaler.
- The piercing of the capsule may produce small capsule pieces. Some of these small pieces may pass through the screen of your MRX003-R into your mouth or throat when you breathe in your medicine. It is not harmful if these pieces are swallowed or inhaled.

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



Figure H

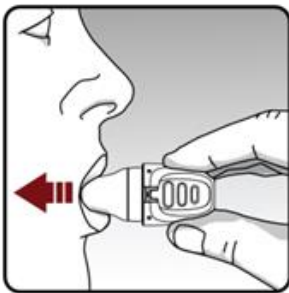


Figure I

Breathe out completely in 1 breath, emptying your lungs of any air. (see Figure H)

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.** (see Figure I)
- 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. Resume normal breathing. Repeat step 4 once more, in order to empty the capsule completely.

Important: Do not press the piercing button again. Remember: To get your full medicine dose each day, you must breathe in 2 times from the same capsule. Make sure you breathe out completely each time before you breathe in from your dry powder inhaler.

Caring for and storing your Dry Powder Inhaler:

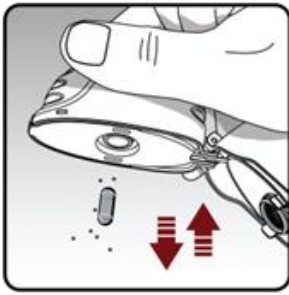


Figure J

After taking your daily dose, open the mouthpiece and tip out the used capsule without touching it, into your rubbish bin.

- Remove any capsule pieces or powder build up, without touching it, by turning your dry powder inhaler upside-down and gently, but firmly, tapping it. (see Figure J)
- Close the mouthpiece and dust cap for storage.

Store the dry powder inhaler at ambient temperature (not more than 30°C).

Do not store your dry powder inhaler and tiotropium capsules (blisters) in a damp moist place. Always store tiotropium capsules in the sealed blisters.

Cleaning your dry powder inhaler:

Clean the dry powder inhaler monthly. (see Figure K).

- **Do not** use cleaning agents or detergents.
- **Do not** place your dry powder inhaler in the dishwasher for cleaning.

It takes 24 hours to air-dry your dry powder inhaler after you clean it:

- **Do not** use a hair dryer to dry your dry powder inhaler
- **Do not** use your dry powder inhaler when it is wet. If needed, you may clean the outside of the mouthpiece with a clean damp cloth.

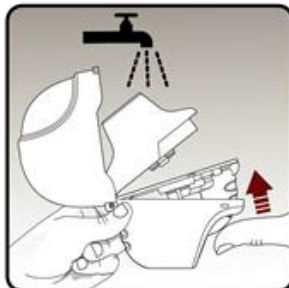


Figure K

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.
- 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. All parts of the dry powder inhaler should be completely dry prior to use.

Blister handling

Each day, separate only 1 of the blisters from the blister card by tearing along the perforated line. (see Figure L)

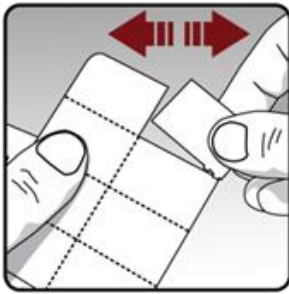


Figure L



Figure M

Remove the tiotropium capsule from the blister (see Figure M):

- Do not cut the foil or use sharp instruments to take out the capsule from the blister.
- Bend 1 of the blister corners with an arrow and separate the aluminium foil layers.
- Peel back the printed foil until you see the whole capsule. Do this only immediately before use.
- If you have opened more than 1 blister to the air, the extra capsule should not be used and should be thrown away.

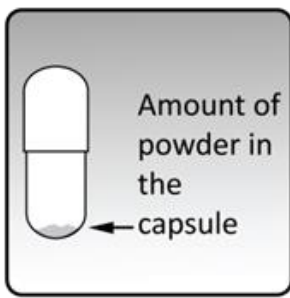


Figure N

Additional Information

Each tiotropium capsule contains only a small amount of powder. (see Figure N) This is 1 full dose taken with two successive breaths.

Do not open the tiotropium capsule or it may not work.

- The dry powder inhaler is intended to be used by adults (minimum 18 years of age) who require pulmonary administration of a medicinal substance.
- There are no known contraindications for the dry powder inhaler
- There are no special precautions for dry powder inhaler disposal
- **Do not** use the device if it is visibly damaged or if an old capsule remains in the device
- Consult a healthcare professional in case of any abnormal reactions to the dry powder inhaler use.

Legal Manufacturer of the dry powder inhaler MRX003-R

Phargentis SA, Via Figino 6, 6917 Barbengo, Switzerland

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