

### 1.5.5.6 Clean Patient Information Leaflet

SCHEDULING STATUS: **S3**

#### **TIOTOR 10 hard capsules for inhalation**

#### **Tiotropium bromide**

**TIOTOR 10 contains sugar (17,98 mg lactose monohydrate per capsule)**

#### **Read all of this leaflet carefully before you start using TIOTOR 10**

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor, pharmacist, nurse or other healthcare provider.
- TIOTOR 10 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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

1. What TIOTOR 10 is and what it is used for
2. What you need to know before you use TIOTOR 10
3. How to use TIOTOR 10
4. Possible side effects
5. How to store TIOTOR 10
6. Contents of the pack and other information

#### **1. What TIOTOR 10 is and what it is used for**

TIOTOR 10 contains tiotropium bromide.

TIOTOR 10 is a medicine used to treat chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. COPD is a chronic lung disease that causes shortness of breath and coughing. As COPD is a chronic disease you should take TIOTOR 10 every day and not only when you have breathing problems or other symptoms of COPD.

## **2. What you need to know before you use TIOTOR 10**

### **Do not use TIOTOR 10**

- if you are allergic (hypersensitive) to tiotropium, its active ingredient, or to any other ingredients of TIOTOR 10 (listed in section 6).
- if you are allergic (hypersensitive) to atropine or substances related to it, e.g. ipratropium or oxitropium.
- if you are younger than 18 years, as safety and effective use of TIOTOR 10 has not been established.

### **Warnings and precautions**

Tell your doctor or healthcare professional before using TIOTOR 10 if:

- you have a sudden attack of breathlessness or wheezing.
- you have immediate allergic reactions such as rash, swelling, itching, wheezing or breathlessness.
- you suffer from narrow angle glaucoma, prostate problems or have difficulty passing urine.
- you have tightness of the chest, coughing, wheezing or breathlessness immediately after inhalation.
- 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. This is important to decide if TIOTOR 10 is the right medicine for you to take.
- you have problems with your kidneys, please consult your doctor.
- you have dry mouth, which has been observed with anti-cholinergic treatment, as this may in the long term be associated with dental caries. Therefore, please remember to pay attention to oral hygiene.
- 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 TIOTOR 10 and immediately consult your doctor, preferably an eye specialist, when signs and symptoms of narrow-angle glaucoma appears.
- Do not use TIOTOR 10 more frequently than once daily.

### **Children and adolescents**

TIOTOR 10 is not recommended for children and adolescents under 18 years.

### **Other medicines and TIOTOR 10**

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

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

No specific side effects have been reported when TIOTOR 10 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, breastfeeding and fertility**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using TIOTOR 10.

### **Driving and using machines**

TIOTOR 10 may cause dizziness, blurred vision or headache which may influence your ability to drive and use machines.

It is not always possible to predict to what extent TIOTOR 10 may interfere with your daily activities. You should ensure that you do not engage in the driving a vehicle or use machines until you are aware of the measure to which TIOTOR 10 affects you.

### **TIOTOR 10 contains lactose monohydrate**

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 TIOTOR 10**

Do not share medicines prescribed for you with any other person.

Always use TIOTOR 10 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 (13 micrograms of tiotropium) once a day. Do not use more than the recommended dose.

The Zephir inhaler device, which you should put the TIOTOR 10 capsule into, makes holes in the capsule and allows you to breathe in the powder.

Make sure that you have a Zephir Inhaler and that you can use it properly.

Make sure that you do not blow into the Zephir Inhaler.

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

You should try to use the capsule at the same time every day. This is important because TIOTOR 10 is effective over 24 hours.

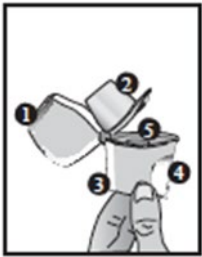
The capsules are only for inhalation and not for oral intake. Do not swallow the capsules.

TIOTOR 10 is not recommended for children and adolescents under 18 years.

When taking TIOTOR 10, 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.

### **Zephir Inhaler – Instructions for use**



1. Dust cap
2. Mouthpiece
3. Base
4. Piercing button
5. Centre chamber

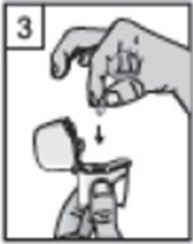
1. Pull the dust cap upwards.



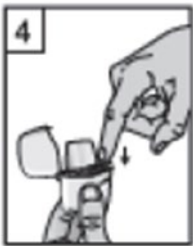
2. Hold the base of the inhaler firmly and open the mouthpiece by pulling it upwards, in the direction of the arrow.



3. Place one capsule in the capsule-shaped compartment in the base of the inhaler.



4. Close the mouthpiece until you hear a click, leaving the dust cap open.



5. Hold the inhaler with the mouthpiece upwards, and firmly press the piercing button completely in once.

Release the button. This will pierce the capsule.



6. Breathe out fully. It is important to do this away from the mouthpiece.

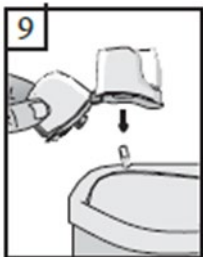


7. Place the mouthpiece in your mouth and tilt your head in an upright position. Close your lips around the mouthpiece and breathe in slowly and deeply enough to hear or feel the capsule vibrating inside the compartment.



8. Hold your breath for as long as you comfortably can while taking the inhaler out of your mouth. Then breathe normally. Repeat steps 6 to 8 to empty the capsule completely.

9. After use, tip out the empty capsule. Close the mouthpiece and dust cap, and store your Zephir inhaler.



TIOTOR 10 capsules contain only a small amount of powder, so that the capsule is only partially filled.

If necessary, the patient may wipe the mouthpiece of the Zephir inhaler after use with a dry cloth or tissue.

#### **If you use more TIOTOR 10 than you should**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you inhale from more than 1 capsule of TIOTOR 10 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 a dose of TIOTOR 10**

Do not use a double dose to make up for forgotten individual doses.

### **If you stop taking TIOTOR 10**

Before you stop using TIOTOR 10, you should talk to your doctor or your pharmacist. If you stop using TIOTOR 10 the signs and symptoms of COPD may worsen.

### **4. Possible side effects**

TIOTOR 10 can have side effects.

Not all side effects reported for TIOTOR 10 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using TIOTOR 10, please consult your healthcare provider for advice.

If any of the following happens, stop using TIOTOR 10 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to TIOTOR 10.

You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

#### *Frequent*

- dry mouth: this is usually mild

#### *Less frequent*

- dizziness
- headache
- taste disorders
- difficulty in sleeping (insomnia)
- blurred vision



- increase of the measured eye pressure
- seeing halos around lights or coloured images in association with red eyes (glaucoma)
- irregular heartbeat (atrial fibrillation / supraventricular tachycardia)
- faster heartbeat (tachycardia)
- feeling your heartbeat (palpitations)
- sore throat (pharyngitis)
- hoarseness (dysphonia)
- cough
- 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)
- heartburn
- constipation
- fungal infections of the oral cavity and throat (oropharyngeal candidiasis)
- 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)
- hives
- swelling in the legs
- difficulty passing urine (urinary retention)
- painful urination (dysuria)
- infections of the urinary tract

### *Side effects with unknown frequency*

- dehydration
- tooth decay (dental caries)
- infections or ulcerations of the skin
- dryness of the skin
- swelling of joints
- mouth ulceration (small lesions that develop in your mouth)
- pharolaryngeal pain (discomfort and irritation of the throat and voicebox)
- itchy skin

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

### **Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of TIOTOR 10.

### **5. How to store TIOTOR 10**

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

Keep the bottle tightly closed. Store in the original package to protect from moisture.

Do not refrigerate or freeze.

30 capsules in HDPE bottle: use capsules within 60 days

15 capsules in HDPE bottle: use capsules within 30 days

Do not use after the expiry date stated on the label / carton / bottle.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## **6. Contents of the pack and other information**

### **What TIOTOR 10 contains**

The active substance is tiotropium bromide. Each hard capsule for inhalation contains 16 micrograms of tiotropium bromide equivalent to 13 micrograms of tiotropium. The delivered dose is 10 micrograms of tiotropium per capsule.

The other ingredients are lactose monohydrate (capsule powder).

Capsule shell composed of hydroxypropylmethylcellulose (HPMC), commonly known as hypromellose.

### **What TIOTOR 10 looks like and contents of the pack**

TIOTOR 10 is colourless and transparent, size 3 capsules, containing white powder.

Cartons containing a Zephir Inhaler device and 15 or 30 hard capsules for inhalation.

The capsules are packaged in plastic (HDPE) bottles closed with a polypropylene screw cap with PE safety ring and a LDPE desiccant capsule containing silica gel.

Zephir Inhaler Device: The inhaler consists of a green cap and lower, white mouthpiece and body and perforating system with 2 needles. The internal grid includes a pin. The push-bottom is white. The Zephir inhaler is a single dose inhalation device made from plastic materials (ABS) and stainless steel.

### **Holder of Certificate of Registration**

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