PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S3**

TIORES

Tiotropium

Capsule for inhalation

Contains sugar (Lactose monohydrate, 18 mg)

Read all of this leaflet carefully before you start using TIORES

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- TIORES 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 TIORES is and what is it used for
2. What you need to know before you use TIORES
3. How to use TIORES
4. Possible side effects
5. How to store TIORES
6. Contents of the pack and other information

1. What TIORES is and what it contains

TIORES is used to treat the symptoms of chronic obstructive pulmonary disease (often referred to as COPD).

With COPD the airflow to the lungs is restricted and this causes symptoms such as coughing and breathlessness.

TIORES works by opening up the air passages in your lungs so that air can flow into your lungs more freely.

2. What you need to know before you use TIORES

Do not use TIORES:

- If you are hypersensitive (allergic) to tiotropium or any of the other ingredients of TIORES (see Section 6).
- If you are hypersensitive (allergic) to atropine or medicines related to atropine, such as ipratropium or oxitropium.
- If you are a child.

Take special care with TIORES:

- If you experience immediate allergic reactions, such as rash, swelling, itching, wheezing or breathlessness, which may occur after using TIORES, please consult your doctor immediately.
- If your breathing gets worse directly after using TIORES, stop using it and tell your doctor immediately.
- If you have prostate problems or have difficulty passing urine.
- If you have glaucoma (causing increased pressure in the eye).
- If you have problems with your kidneys.
- If TIORES accidentally enters your eye, it can cause an acute attack of narrow-angle glaucoma (an eye condition). If any powder does get into your eyes, you should wash your eyes in lukewarm water immediately. If you experience any eye pain or discomfort, blurred vision, seeing circles around lights or coloured images in association with red eyes, you should stop using TIORES and immediately consult your doctor, preferably an eye specialist.
- If you experience a dry mouth after using TIORES. In the long term a dry mouth can increase dental caries, therefore you must remember to pay extra attention to oral hygiene. You can

also try chewing sugar free gums, to prevent a dry mouth.

- If you are an elderly person, some of the side effects of TIORES may be more profound.
- Never use TIORES more frequently than once a day.

Other medicines and TIORES

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

Tell your doctor or pharmacist if you are currently using any medicines classified as anticholinergics. Anticholinergics include, among other things, medicines used to treat:

- Asthma and COPD (ipratropium).
- Incontinence (oxybutynin, solifenacin, tolterodine).
- Stomach cramps (dicycloverine).
- Muscular spasms (orphendadrine).
- Sleep disorders (doxylamine, diphenhydramine).

Pregnancy and breastfeeding:

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 health care provider for advice before using TIORES.

Pregnancy

Safety of TIORES during pregnancy has not been established.

Breastfeeding

Safety of TIORES during lactation has not been established.

Driving and using machinery:

TIORES may cause dizziness, blurred vision or headache, which may impair your ability to drive a vehicle or use machines. Take special care before performing tasks requiring your attention.

It is not always possible to predict to what extent TIORES may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which TIORES affects them.

TIORES contains sugar (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 TIORES

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

Always take TIORES exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

TIORES capsules are for inhalation use only. Do not swallow TIORES capsules.

Inhale the contents of one capsule once a day, at the same time each day, using your Zephir inhaler.

The Zephir inhaler, which you should put the TIORES capsule into, makes holes in the capsule and allow you to breathe in the powder.

Instructions for using your Zephir inhaler:

Your doctor or healthcare practitioner will demonstrate to you how to use TIORES capsules, using your Zephir inhaler. Only use the Zephir inhaler for TIORES capsules. Do not use the Zephir inhaler to take any other medication. Discard your Zephir inhaler after 30 uses. You will receive a new Zephir inhaler every time you receive a new supply of TIORES.



Dust cap

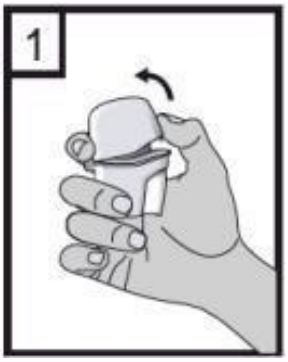
Mouthpiece

Base

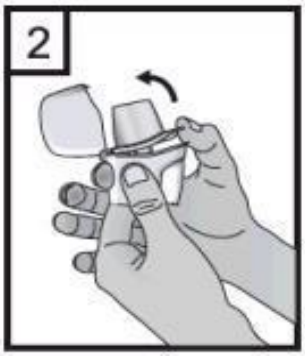
Piercing button

Centre chamber

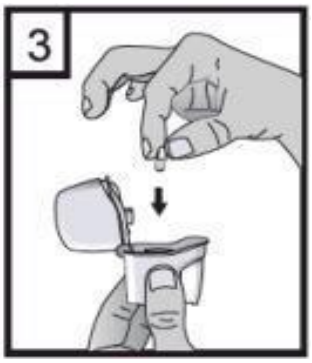
Step 1: Pull the cap upwards.



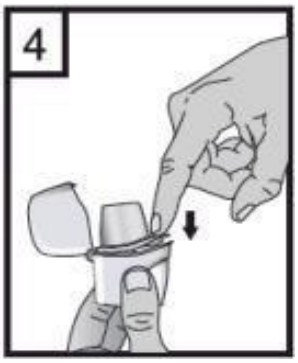
Step 2: Hold the base of the inhaler firmly and open the mouthpiece by pulling it upwards in the direction of the arrow to open it.



Step 3: Remove a TIORES capsule from the bottle immediately before use. Place one capsule in the capsule-shaped compartment in the base of the inhaler. It doesn't matter which way the capsule is placed in the chamber.

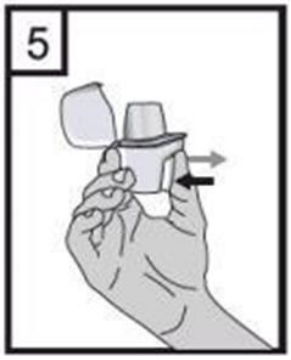


Step 4: Close the mouthpiece until a click is heard, leaving the cap open



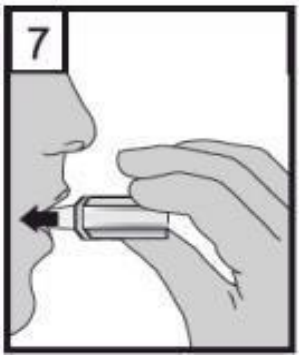
Step 5: Hold the inhaler with the mouthpiece upwards, and press the piercing button

completely in only once. Release the button. This is for making holes in your TIORES capsule and allowing you to breathe in the powder.



Step 6: Breathe out fully. It is important to do this away from the mouthpiece. Make sure that you do not blow into the Zephir inhaler at any time.

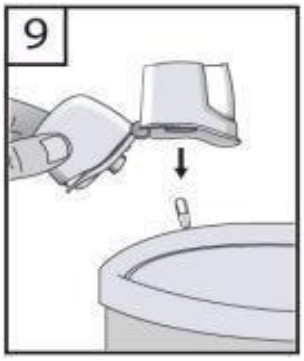
Step 7: Place the mouthpiece in your mouth and keep your head in an upright position. Close your lips around the mouthpiece and breathe in slowly and deeply enough, to hear or feel the TIORES capsule vibrating inside the compartment. Hold your breath for as long as you comfortably can whilst taking the Zephir inhaler out of your mouth.
Resume normal breathing.



Step 8: Repeat steps 6 and 7 (inhale for a second time from the same capsule) in order to empty the

capsule completely.

Step 9: After use, open the mouthpiece again. Tip out and dispose of the empty TIORES capsule. Close the mouthpiece and cap, and store the Zephir inhaler.



Your doctor will tell you how long your treatment with TIORES will last. If you feel that your breathing is worsening or if you have the impression that the effect of TIORES is too strong or too weak, tell your doctor or pharmacist.

If you use more TIORES than you should:

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

Take this leaflet and the rest of the remaining capsules with you so the doctor will know what you have used.

If you forget to use TIORES:

Use TIORES as soon as you remember on the same day. If it is almost time for your next usual dose, skip the missed dose and continue using TIORES at your regular time.

Do not use a double dose of TIORES at the same time or on the same day, to make up for the forgotten dose.

Effects when treatment with TIORES is stopped:

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

4. Possible side effects

TIORES can have side effects.

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

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

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to TIORES. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequent:

- Chest pain.

Less frequent:

- Irregular heartbeat.

- Changes in the way your heart beats (e.g. faster heart beat).
- Feeling your heartbeat.
- Painful urination.
- Difficulty passing urine.
- Urinary tract infections.
- Tightness of the chest, associated with coughing, wheezing, or breathlessness immediately after inhalation.
- Seeing halos around lights or coloured images in association with red eyes.
- Increase in the measured eye pressure.
- Blockage of intestines or absence of bowel movements.
- High blood sugar levels.
- High levels of cholesterol in the blood.
- Feeling down.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent:

- Dry mouth.
- Upper respiratory tract infection.
- Sore throat.
- Inflammation of the sinuses.
- Hay fever.
- Indigestion.

Less frequent:

- Fever.

- Fluid retention.
- Dizziness.
- Headache.
- Tickling or prickling sensation (pins and needles).
- Taste disorders.
- Difficulty in sleeping.
- Blurred vison.
- Inflammation of larynx.
- Coughing.
- Nose bleeds.
- Hoarseness.
- Constipation, nausea, vomiting, abdominal pain.
- Inflammation of the gums, tongue or mouth.
- Difficulties swallowing.
- Thrush in the mouth or throat.
- Rash, or itching.
- Muscle or leg pains.

Frequency unknown:

- Depletion of body water.
- Tooth decay.
- Swelling of the joints.
- Skin infection.
- Dry 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 or pharmacist.

You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of TIORES.

5. How to store TIORES

- Store all medicines out of reach of children.
- Store at or below 25 ºC
- Once opened, keep the bottle tightly closed. Store in the original bottle to protect from moisture.
- Discard the Zephir inhaler after 30 uses
- Do not use after the expiry date printed on the carton.
- 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 TIORES contains:

Each capsule for inhalation contains 15,6 µg tiotropium bromide equivalent to 13 µg tiotropium, with a delivered dose of 10 µg tiotropium.

The other ingredient is lactose monohydrate.

What TIORES looks like and contents of the pack

What TIORES looks like:

Colourless and transparent, size 3 capsules, containing white powder.

Contents of the pack:

A white HDPE bottle and white polypropylene screw-cap closure, with a polyethylene seal. The screw-cap includes a desiccant compartment containing silica gel.

Each HDPE bottle is packed in an outer carton, together with a green and white Zephir inhaler.

Pack sizes: 15 capsules and 1 inhaler, 30 capsules and 1 inhaler, or 3 x 30 capsules and 3 inhalers.

Not all pack sizes may be marketed.

Holder of certificate of registration

Activo Health (Pty) Ltd.

Block B, Arena Office Park

272 West Avenue

Centurion

0157

South Africa

+27 12 848 7600

This leaflet was last revised in

Date of registration: 28 November 2019

Date of revision: 23 July 2025

Registration number

50/10.2.1/0671