Patient information leaflet for NEUMOTROPIO

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

NEUMOTROPIO 10 µg inhalation powder, hard capsules

Tiotropium bromide

Contains sugar: each capsule contains 18 mg lactose monohydrate.

Read all of this leaflet carefully before you start using NEUMOTROPIO:

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

1. What NEUMOTROPIO is and what it is used for

NEUMOTROPIO is an inhaled medicine that helps to open your airways and makes it easier to get air in and out of the lungs. NEUMOTROPIO works by opening up the air passages in your lungs so that air can flow into your lungs more freely.

NEUMOTROPIO 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. COPD also includes the conditions:

- Chronic bronchitis (inflammation of the lining of the bronchial tubes, causing chest tightness and coughing).
- Emphysema (a condition in which the air sacs of the lungs are damaged and enlarged, causing breathlessness).

2. What you need to know before you use NEUMOTROPIO

Do not use NEUMOTROPIO:

- If you are hypersensitive (allergic) to tiotropium or any of the other ingredients of NEUMOTROPIO (listed in section 6 of this leaflet).
- If you are hypersensitive (allergic) to atropine or medicines related to atropine, such as ipratropium or oxitropium.
- If you are a child.

Warnings and precautions:

Take special care with NEUMOTROPIO:

- If you experience immediate allergic reactions, such as rash, swelling, itching, wheezing or breathlessness, which may occur after using NEUMOTROPIO, please consult your doctor immediately.
- If you have suffered from a heart attack (myocardial infarction) during the last 6 months, or suffer from any unstable or life-threatening, irregular heartbeat or severe heart failure in the past year,

please inform your doctor. This is important so that your doctor can decide whether or not NEUMOTROPIO is the right treatment for you to use.

- If you are breathless after using NEUMOTROPIO, or if you experience tightness of the chest, coughing or wheezing after inhalation, please tell your doctor immediately (see section 4).
- 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 NEUMOTROPIO 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 NEUMOTROPIO and immediately consult your doctor, preferably an eye specialist.
- If you experience a dry mouth after using NEUMOTROPIO. 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 gum, to prevent a dry mouth.

NEUMOTROPIO 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.

Never use NEUMOTROPIO more frequently than once a day.

Children:

NEUMOTROPIO is not recommended for children (see section “Do not use NEUMOTROPIO”).

Other medicines and NEUMOTROPIO:

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

Tell your doctor or pharmacist if you are currently using any medicines classified as anticholinergics.

Anticholinergics include medicines used to treat:

- Asthma and COPD
- Incontinence
- Stomach cramps
- Muscular spasms
- Sleep disorders.

NEUMOTROPIO with food and drink:

There are no known interactions between NEUMOTROPIO, food and drink.

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 NEUMOTROPIO.

You should not use NEUMOTROPIO if you are pregnant or breastfeeding.

Driving and using machines:

NEUMOTROPIO 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, until you know how NEUMOTROPIO will affect you.

3. How to use NEUMOTROPIO

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

Always use NEUMOTROPIO exactly as your doctor has told you. Check with your doctor if you are not sure.

The recommended dose is to inhale the contents of one capsule once a day, at the same time each day, using the provided Zephir inhaler. Do not use more than the recommended dose.

NEUMOTROPIO capsules are for inhalation use only. Do not swallow NEUMOTROPIO capsules. Each capsule contains only a small amount of powder. Do not open the capsule or it may not work.

The Zephir inhaler, which you should put the NEUMOTROPIO capsule into, makes holes in the capsule and allow you to breathe in the powder.
NEUMOTROPIO capsules must only be inhaled using the Zephir inhaler.
Do not use any other inhalers to administer NEUMOTROPIO capsules. Make sure you know how to use the Zephir inhaler properly. See “Instructions for using NEUMOTROPIO capsules with the Zephir inhaler” below.

If you have any problems using the Zephir inhaler, ask your doctor, pharmacist or health care provider to show you how it works.

Make sure you do not blow into the Zephir inhaler. When using NEUMOTROPIO, take care not to let any of the powder enter your eyes (see section 2 “Warnings and precautions”).

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

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

Instructions for using NEUMOTROPIO capsules with the Zephir inhaler:

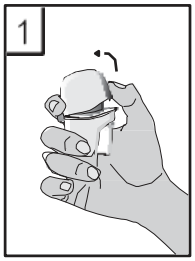
- The Zephir inhaler enables you to inhale the medicine contained in the NEUMOTROPIO capsule that your doctor has prescribed for your breathing problems.

- The Zephir inhaler should only be used with the bottle of capsules that will either be provided in the same pack, or in the pack bundled separately with the inhaler pack. Do not reuse the inhaler for another bottle of capsules.
- Discard the Zephir inhaler after 15 uses (if used with a 15 capsule bottle) or 30 uses (if used with a 30 capsule bottle).

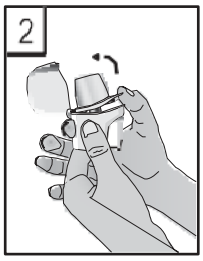


1. Dust cap
2. Mouthpiece
3. Base
4. Piercing button
5. Centre chamber

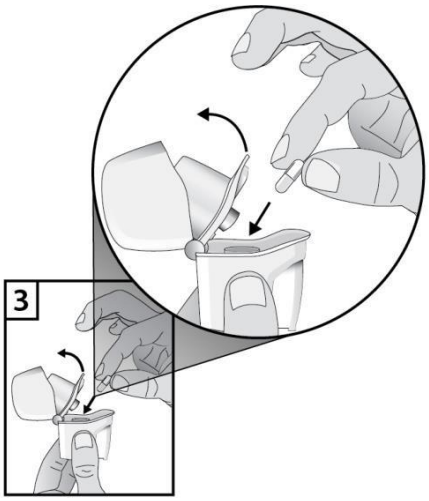
Step 1: Lift the cap upwards.



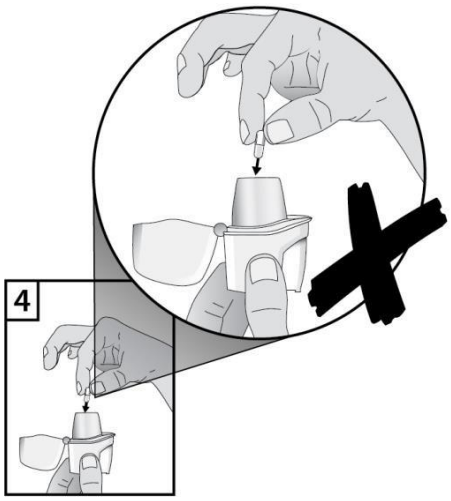
Step 2: Hold the base of the inhaler firmly and open the mouthpiece by lifting it upwards in the direction of the arrow to open it.



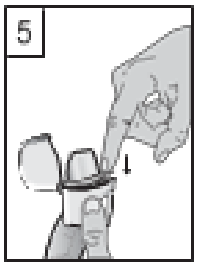
Step 3: Remove a NEUMOTROPIO capsule from the bottle immediately before use and close the bottle tightly. Place one capsule in the centre chamber in the base of the inhaler. Do not store the capsule in the Zephir inhaler.



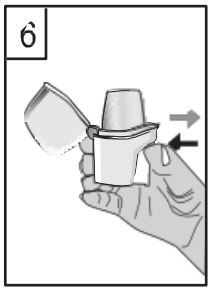
Step 4: To avoid the risk of choking, NEVER place a capsule directly into the mouthpiece.



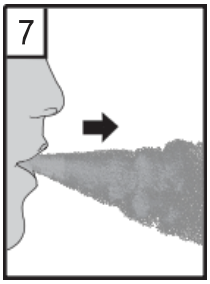
Step 5: Close the mouthpiece until you hear a click, leaving the dust cap open.



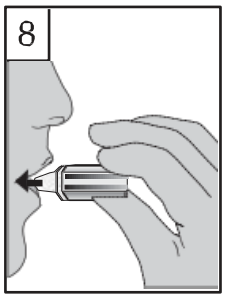
Step 6: Hold the inhaler with the mouthpiece upwards and press the piercing button completely in once. Release the button. This will pierce the capsule and allows the NEUMOTROPIO to be released when you breathe in.



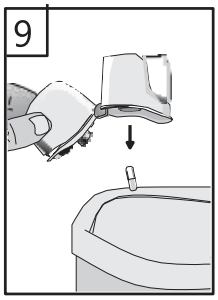
Step 7: Breathe out fully. It is important to do this away from the mouthpiece. Avoid breathing into the mouthpiece at any time.



Step 8: 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 capsule vibrating inside the centre chamber. Hold your breath for as long as you comfortably can whilst taking the inhaler out of your mouth. Then breathe normally. Repeat steps 7 and 8 to empty the capsule completely.



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



If you use more NEUMOTROPIO than you should:

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

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

4. Possible side effects

NEUMOTROPIO can have side effects.

Not all side effects reported for NEUMOTROPIO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using NEUMOTROPIO, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop using NEUMOTROPIO 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.
- Fainting.

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

- Changes in the way your heart beats (e.g. faster heartbeat), irregular heartbeat, feeling your heartbeat (tachycardia).
- Urinary tract infections, difficulty passing urine, painful urination.
- Tightness of the chest, associated with coughing, wheezing, or breathlessness immediately after inhalation (bronchospasm).
- Seeing halos around lights or coloured images in association with red eyes (glaucoma), increase in the pressure measured inside the eye.
- Absence of bowel movements (intestinal obstruction).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Dry mouth.

Less frequent side effects:

- Dizziness, headache, taste disorders.
- Difficulty in sleeping.
- Blurred vison.
- Sore throat (pharyngitis), inflammation of the sinuses (sinusitis), inflammation of the larynx (laryngitis), cough.
- Hoarseness.
- Nose bleeds.
- Indigestion, heartburn.
- Nausea, vomiting, abdominal pain.
- Inflammation of the gums, tongue or mouth.
- Difficulties swallowing.
- Thrush in the mouth or throat.
- Rash or itching.

Frequency unknown:

- Anaphylactic reaction
- Depletion of body water (dehydration).
- Tooth decay.
- Swelling of the joints.
- Skin infection, ulceration of the skin, 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 "**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 NEUMOTROPIO.

5. How to store NEUMOTROPIO

- Store at or below 25 °C.
- Once opened, keep the bottle tightly closed. Store capules in the original bottle to protect from moisture.
- Use capsules within 30 days (15 capsule bottle) or 60 days (30 capsule bottle).
- Discard the Zephir inhaler after 30 uses (or 15 uses, if used in conjunction with the 15 capsule bottle).
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- 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 and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What NEUMOTROPIO contains:

The active ingredient is tiotropium.

Each capsule for inhalation contains a delivered dose of 10 µg tiotropium.

The other ingredients are: lactose monohydrate (capsule contents) and hypromellose (capsule cells).

What NEUMOTROPIO looks like and contents of the pack:

Colourless and transparent, size 3 capsules, partially filled with white powder.

White and opaque 20 mL or 35 mL HDPE bottle with a white and opaque 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, supplied with a Zephir inhaler. The Zephir inhaler is a single dose inhalation device, with a green body, a perforating system of 2 needles, a green cap and a white mouthpiece and push button, made from ABS plastic materials and stainless steel.

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

Holder of certificate of registration:

CIPLA MEDPRO (PTY) LTD.

Building 9

Parc du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662

This leaflet was last revised in:

24 February 2022

Registration number:

51/10.2.1/0143

Date of registration: 20 July 2021

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To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER: The QR Code to be generated and included after approval.