

HOW TO USE TRIXEO AEROSPHERE

If you have been prescribed
TRIXEO AEROSPHERE
by your doctor



Please carefully read the information in the Patient Information Leaflet (PIL) before starting treatment with your Trixio Aerosphere. It contains information that is important for you to know.

LEVAMEDKOL

Would you like to learn more about COPD? Go to: levamedkol.se

What Trixeo Aerosphere is and what it is used for

The Trixeo Aerosphere contains three active substances: formoterol fumarate dihydrate, glycopyrronium, and budesonide.

Formoterol fumarate dihydrate and glycopyrronium belong to a group of medicinal products called “bronchodilators”. These work in different ways to make breathing easier by relaxing the muscles in the lungs and widening the airways (bronchi).

Budesonide belongs to a group of medicinal products called “corticosteroids”. These work by reducing inflammation in your lungs.

Trixeo Aerosphere is an inhaler used for adults with a lung disease called chronic obstructive pulmonary disease (COPD), a chronic disease of the airways of the lungs.

Trixeo Aerosphere is used to make breathing easier and improve symptoms of COPD such as shortness of breath, wheezing and coughing. Trixeo Aerosphere can also prevent acute worsening periods, i.e. prevent COPD symptoms from flaring up (exacerbations).

Trixeo Aerosphere delivers active substances to your lungs when you inhale. If you use this medication regularly twice a day, it will help reduce the effects of COPD in your everyday life.

What you need to know before using a Trixeo Aerosphere



Do not use a Trixeo Aerosphere:

- if you are allergic to formoterol fumarate dihydrate, glycopyrronium, budesonide or any other ingredient in this medicinal product.

Warnings and Precautions

Trixeo Aerosphere is used as a long-term maintenance treatment of COPD. **Do not use it to treat a sudden attack of shortness of breath or wheezing.**

Sudden difficulty breathing

If you experience chest tightness, coughing, wheezing or shortness of breath immediately after using Trixeo Aerosphere, **stop using it and seek medical advice immediately** as this could be a serious condition called paradoxical bronchospasm.

If your shortness of breath, chest tightness, wheezing or cough gets worse while using Trixeo Aerosphere, continue using Trixeo Aerosphere but contact your doctor as soon as possible, as you may need further treatment.

Talk to your doctor before using Trixeo Aerosphere if:

- you have high blood pressure or heart problems
- you have diabetes
- you have a lung infection
- you have thyroid problems
- you have low potassium levels in your blood
- you have prostate problems or difficulty urinating
- you have an eye problem called “narrow-angle glaucoma”
- you have low kidney or liver function

Other medicinal products and Trixeo Aerosphere

Trixeo Aerosphere can affect how certain medicinal products work. Other medicines can also affect how Trixeo Aerosphere works or make you more likely to have side effects.

Always tell your doctor or pharmacist if you are using other medicinal products.

Pregnancy and Breastfeeding

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 using this medicine.

How to use Trixeo Aerosphere

Trixeo Aerosphere is intended for inhalation. Always use this medicinal product as directed by your doctor. Ask your doctor or pharmacist if you are unsure.

How much should you use?

Please read these instructions carefully. Your Trixeo Aerosphere (called “inhaler” in this PIL) may be different from inhalers you have used before. The recommended dose is two puffs twice daily - two puffs in the morning and two puffs in the evening.

It is important that you use your Trixeo Aerosphere every day, even if you do not currently have any symptoms of COPD.

Taken morning and evening



2 INHALATIONS/PUFFS IN THE MORNING



2 INHALATIONS/PUFFS IN THE EVENING

Triexo Aerosphere inhalation spray

Dose indicator

Counts down by 1 each time you spray a puff

Arrow

Indicates the number of puffs remaining

Yellow zone

Order a new inhaler when the arrow is in the yellow zone

Red zone

Discard your inhaler when the arrow points to 0 in the red zone. Do not try to take a puff when the arrow points to 0 because you will not get a full dose

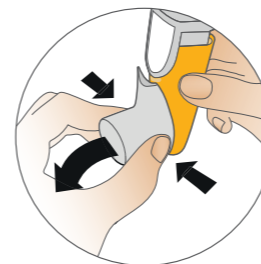
Do not reuse the adapter or use it with medicine containers from other inhalers.



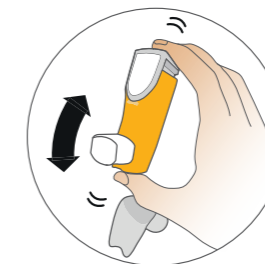
How to use your inhaler

Before first use:

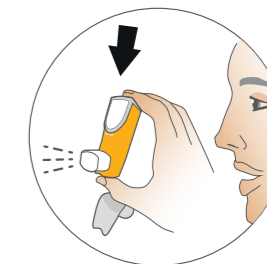
Prime your inhaler before you start using it for the first time to ensure you get the right amount of medicine when you use it.



1. Remove the protective cover.



2a. Shake the inhaler thoroughly.

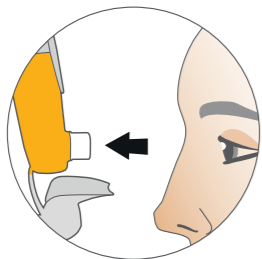


2b. Spray **1 test puff** into the air facing away from you. Repeat **a total of 4 test puffs**, shake the inhaler before each test puff.

Prime your inhaler with **2 test puffs** and shake before each test puff. This should be done after rinsing the inhaler, if it is dropped or if it has not been used for more than 7 days. Extra puffs have been added to allow for priming. Do not skip priming!

Daily use morning and evening:

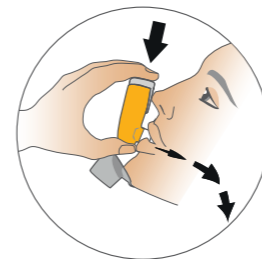
- Daily dose: two puffs in the morning and two puffs in the evening.
- Rinse your mouth with water after each two puffs to prevent yeast infection.



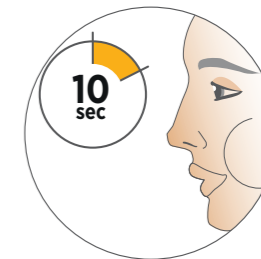
1. Remove the protective cover. **Check that there are no foreign objects in the mouthpiece and, if there are any, remove these before use.**



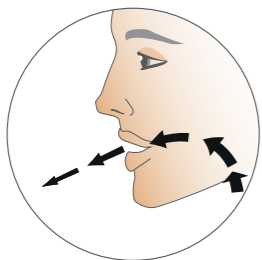
2a. Shake the inhaler thoroughly before each puff.



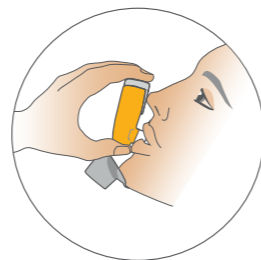
2d. Begin to breathe in deeply and slowly as you spray **1 puff**. Keep breathing in until you can't breathe in anymore.



2e. Hold your breath for as long as you can, up to **10 seconds**.



2b. Breathe out completely.



2c. Insert the mouthpiece in your mouth and close your lips around the mouthpiece. Tilt your head back and hold your tongue under the mouthpiece.



3&4. Repeat step 2 for a second puff. Put the protective cover back in its place.



5. Rinse your mouth with water. Spit out the water. **Do not swallow.**

Using your Triexo Aerosphere inhaler:

Use of Triexo Aerosphere with an inhaler spacer

If you have difficulty breathing in and pressing the inhaler at the same time, talk to your doctor or pharmacist. You may be able to use a spacer together with your inhaler.

If you have taken an excess dose of your Triexo Aerosphere

If you have taken more Triexo Aerosphere doses than directed, seek medical or pharmacist advice immediately. You may need medical attention. You may feel your heart beat faster than normal, feel shaky, have blurred vision, dry mouth, headache or feel nauseous.

If you forget to take Triexo Aerosphere

Do not take a double dose to make up for a missed dose. Take it as soon as you remember. If, however, it is almost time to take the next dose, skip the forgotten dose. Do not take more than two puffs twice daily.

If you stop using Triexo Aerosphere

This medicine is intended for long-term use. Use this medicine for as long as your doctor tells you to. It will only be effective while you use it.

Do not stop taking this medicine unless your doctor tells you otherwise, even if you feel better, because your symptoms may get worse. If you wish to stop the treatment, talk to your doctor first.

Instructional video

If you would like further advice and instructions on how to use your Triexo Aerosphere, you can find an instructional video at www.medicininstruktioner.se/astrazeneca/trixeo/

How to store your Triexo Aerosphere

Keep this medicine out of sight and reach of children.

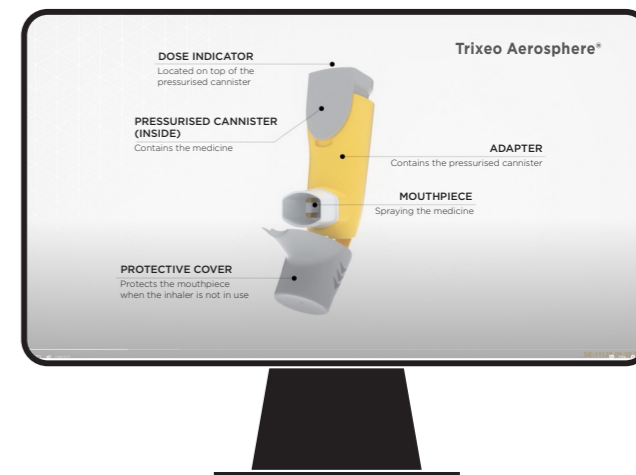
Use before the expiry date that is printed on the carton, bag or pressurised cannister after "EXP". The expiry date is the last day of the month shown.

The inhaler can be used for up to 3 months after opening. Store the inhaler inside the sealed bag - only take the inhaler out of the sealed bag immediately before first use. Write the date the bag was opened in the place shown on the inhaler label.

Store at maximum 30 °C. To be stored dry. For best results, the inhaler should be at room temperature before use.

Do not destroy, puncture or burn the pressurised cannister, even if it seems to be empty. Do not use or store the cannister close to heat or a naked flame.

Do not dispose of medicines down a drain or together with household waste. Ask a pharmacist how to dispose of medicines that are no longer used. These measures help to protect the environment.



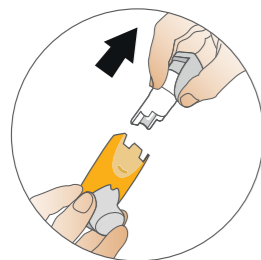
Scan the QR code with your smartphone camera to link directly to the instructional video:



Weekly rinsing

Rinse the adapter weekly:

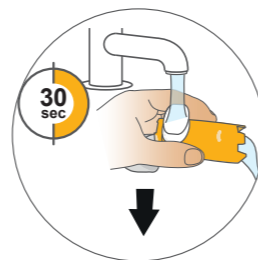
- Rinse the yellow adapter weekly to prevent the medicine clumping and blocking the mouthpiece.
- Do not let the pressurised cannister get wet.
- Prime the inhaler again after rinsing (see page 5).



1. Remove the pressurised cannister and set aside. **Do not let it get wet.**



2. Remove the protective cover.



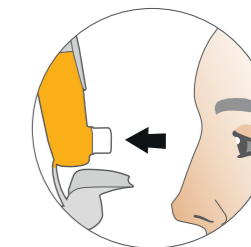
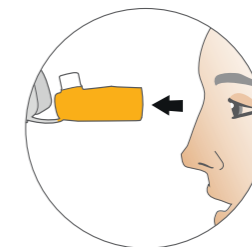
3. Rinse the mouthpiece with warm water for 30 seconds, then rinse the top of the adapter for 30 seconds. **Rinse for 60 seconds in total.**



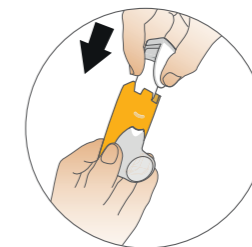
4. Shake off as much water as possible. Do not wipe dry with a towel or paper tissue.



6. Leave to air dry preferably overnight. Do **not** put the pressurised cannister back into the adapter if it is still damp.



5. Check for any medicine clumping in the adapter and mouthpiece. If you see any clumps, repeat rinsing steps 3 to 5.



Shake and test puff 2 times.

7&8. When the adapter is dry, **first replace the protective cover** and then gently push the pressurised cannister down into the adapter.

Prime the inhaler again (see page 5) by spraying **2 test puffs**. Shake between each test puff.

Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody may experience any. To learn more about reported side effects for this medicine, read the PIL that comes with your inhaler.

Sudden difficulty breathing:

- If you experience breathing difficulties immediately after using Trixeo Aerosphere such as chest tightness, coughing, wheezing or shortness of breath, **stop using this medicine** and **seek medical advice immediately**.

Allergic reactions:

- swelling of the face, especially around the mouth (swelling of the tongue or throat may make swallowing difficult)
- hives together with breathing difficulties
- suddenly feeling faint

These symptoms may be signs of an allergic reaction that can be serious. Stop using this medicine and seek medical attention immediately if you experience any of the serious side effects listed above.

Common (may affect up to 1 in 10 users)

- fungal infection of the mouth (oral thrush). Rinsing your mouth with water immediately after using Trixeo Aerosphere can help prevent this.
- feeling of anxiety

- sleep difficulties
- nausea
- headache
- cough or hoarse voice
- muscle cramps
- you feel your heartbeat (palpitations)
- high blood sugar levels (shown in tests)
- pain when urinating and frequent urge to urinate (may be signs of a urinary tract infection)
- pneumonia.

Tell your doctor if you have experienced any of the following while using Trixeo Aerosphere, they could be symptoms of an infection in the lungs:

- fever or chills
- increased mucous production, changed colour of your mucous
- increased coughing or increased breathing difficulties.

Reporting of side effects

If you experience any side effects, consult your doctor, nurse or pharmacist. This also applies to any side effects that are not mentioned in the leaflet. You can also report side effects directly to the Swedish Medical Products Agency, www.lakemedelsverket.se. By reporting side effects, you can help increase information about drug safety.

Trixeo Aerosphere® is an inhalation spray that contains three active substances called glycopyrronium, formoterol fumarate dihydrate, and budesonide. Glycopyrronium and formoterol fumarate belong to a group of medicines called long-acting bronchodilators. Budesonide belongs to a group called corticosteroids.

The Trixeo Aerosphere® is used to make breathing easier and improve symptoms of COPD, such as shortness of breath, wheezing and coughing. The Trixeo Aerosphere® can also prevent acute worsening periods, flare-ups of COPD symptoms (exacerbations).

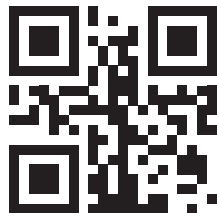
The Trixeo Aerosphere® is not intended for the treatment of acute episodes of bronchospasm, i.e. it is not intended for needs-based treatment, nor for the treatment of asthma.

Carefully read the information in the PIL before starting your treatment with Trixeo Aerosphere®. It contains information that is important for you to know.

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Notes



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