Package leaflet: Information for the patient

Trixeo Aerosphere® 5 micrograms/7.2 micrograms/160 micrograms, pressurised inhalation, suspension
formoterol fumarate dihydrate/glycopyrronium/budesonide

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

1. What Trixeo Aerosphere is and what it is used for

Trixeo Aerosphere contains three active substances: formoterol fumarate dihydrate, glycopyrronium, and budesonide.
- Formoterol fumarate dihydrate and glycopyrronium belong to a group of medicines called 'bronchodilators'. They work in different ways to prevent tightening of the muscles around the airways, making it easier for air to get in and out of the lungs.
- Budesonide belongs to a group of medicines called 'corticosteroids'. These work by reducing inflammation in your lungs.

Trixeo Aerosphere is an inhaler that is used for adults with a lung disease called 'chronic obstructive pulmonary disease' (or 'COPD'), a long-term disease of the airways in the lungs.

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

Trixeo Aerosphere delivers the active substances into your lungs as you breathe in. If you use this medicine regularly twice a day, it will help to reduce the effects of COPD on your everyday life.

2. What you need to know before you use Trixeo Aerosphere

Do not use Trixeo Aerosphere
- if you are allergic to formoterol fumarate dihydrate, glycopyrronium, budesonide or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Trixeo Aerosphere is used as a long-term maintenance treatment for COPD. **Do not use it to treat a sudden attack of breathlessness or wheezing.**

Immediate breathing difficulties
If you get tightness of the chest, coughing, wheezing or breathlessness immediately after using Trixeo Aerosphere, **stop using it and tell your doctor straight away** (see 'Serious side effects' at the top of Section 4 for more information).

If your breathlessness, tightness of the chest, wheezing or coughing is getting worse while using Trixeo Aerosphere, you should continue to use Trixeo Aerosphere but contact your doctor as soon as possible, as you may need additional 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 problems with your thyroid gland
- you have low levels of potassium in your blood
- you have prostate problems or any problems passing urine
- you have an eye problem called 'angle-closure glaucoma'
- you have kidney or liver problems.

Talk to your doctor if you think any of these may apply to you.

Children and adolescents
Trixeo Aerosphere has not been studied in children and adolescents. Do not give this medicine to children or adolescents below the age of 18 years.

Other medicines and Trixeo Aerosphere
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, and herbal medicines. This is because Trixeo Aerosphere can affect the way some medicines work. Also some medicines can affect how Trixeo Aerosphere works, or make it more likely that you will have side effects.

Tell your doctor or pharmacist if you are taking any of the following:
- medicines called beta-blockers (such as atenolol or propranolol), that may be used for high blood pressure or heart problems, or to treat glaucoma (such as timolol)
- medicines which are used to treat fungal infections – such as ketoconazole or itraconazole
- medicines which are used to treat HIV infection – such as ritonavir or cobicistat
- medicines that lower the amount of potassium in your blood, such as:
  - corticosteroids that you take by mouth (such as prednisolone),
  - diuretics – medicines that increase urine production (such as furosemide or hydrochlorothiazide), which can be used for treating high blood pressure,
  - some medicines used to treat breathing problems (such as theophylline) – called 'methylxanthines',
- any medicines that work in the same way as Trixeo Aerosphere – such as tiotropium, ipratropium, aclidinium, umeclidinium or salmeterol, arformoterol, vilanterol, olodaterol or indacaterol. Do not use Trixeo Aerosphere if you already use these medicines.
- medicines which are used to treat heart rhythm problems – such as amiodarone
- medicines which can change some electrical activity of the heart (called the 'QT interval') – such as medicines for:
  - depression (such as monoamine oxidase inhibitors or tricyclic antidepressants),
  - bacterial infections (such as erythromycin, clarithromycin or telithromycin),
  - allergic reactions (anti-histamines).

If any of the above applies to you, or if you are not sure, talk to your doctor or pharmacist before using Trixeo Aerosphere.

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.

Do not use Trixeo Aerosphere if you are pregnant unless your doctor tells you that you can.

Do not use this medicine if you are breast-feeding unless your doctor tells you that you can.

Driving and using machines
It is unlikely that this medicine will affect your ability to drive or use machines. However, dizziness is an uncommon side effect which should be taken into account when driving or using machines.

3. How to use Trixeo Aerosphere

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How much to use
The recommended dose is two puffs twice a day – two puffs in the morning and two puffs in the evening.

It is important to use Trixeo Aerosphere every day – even if you have no COPD symptoms at the time.

Remember: Always rinse your mouth with water after using Trixeo Aerosphere. This is to remove any medicine which is left in the mouth. Spit this water out – do not swallow.

How to use
Trixeo Aerosphere is for inhalation use.
Please read the 'Instructions for Use' at the end of this leaflet. If you are not sure how to use Trixeo Aerosphere, talk to your doctor or pharmacist.

Using Trixeo Aerosphere with a spacer
You may find it difficult breathing in and pressing the inhaler at the same time. If this happens, talk to your doctor or pharmacist. It may help to use a 'spacer' with your inhaler.

If you use more Trixeo Aerosphere than you should
If you have used more Trixeo Aerosphere than you should, talk to a doctor or pharmacist straight away. You may need medical attention. You may notice that your heart is beating faster than usual, you feel shaky, you have problems with your sight, you have a dry mouth or you have a headache or feel sick (nausea).

If you forget to use Trixeo Aerosphere
Do not take a double dose to make up for a forgotten dose. Take it as soon as you remember.

However, if it is nearly time for your next dose, skip the missed dose. Do not take more than two puffs twice a day on the same day.

If you stop using Trixeo Aerosphere
This medicine is for long-term use. Use this medicine for as long as your doctor tells you to. It will only be effective as long as you are using it.

Do not stop unless your doctor tells you to – even if you feel better – as your symptoms may get worse. If you want to stop treatment, talk to your doctor first.

If you have any further questions on the use of this medicine, talk to your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Serious side effects

Uncommon (may affect up to 1 in 100 people)

Immediate breathing difficulties:
- if you get breathing difficulties straight after using Trixeo Aerosphere, such as tightness of the chest, coughing, wheezing or feeling breathless, **stop using this medicine** and **tell your doctor straight away**.

Allergic reactions:
- swelling of your face, particularly around your mouth (swelling of your tongue or throat may make it difficult to swallow)
- rash or hives together with difficulty breathing
- suddenly feeling faint

These symptoms may be signs of an allergic reaction which may become serious. Stop using this medicine and call for medical help straight away if you notice the serious side effects above.

Other side effects

Tell your doctor or pharmacist if you notice any of the following side effects:

Common (may affect up to 1 in 10 people)
- thrush in the mouth (a fungal infection). Rinsing your mouth out with water immediately after using Trixeo Aerosphere may help prevent this.
- feeling anxious
- difficulty sleeping
- feeling sick (nausea)
- headache
- coughing or a hoarse voice
- muscle cramps
- awareness of your heart beating (palpitations)
- high blood sugar levels (as shown in tests)
- painful and frequent urination (may be signs of a urinary tract infection)
- pneumonia (infection of the lung).

Tell your doctor if you have any of the following while using Trixeo Aerosphere, they could be symptoms of a lung infection:
- fever or chills,
- increased mucus production, change in mucus colour,
- increased cough or increased breathing difficulties.

Uncommon (may affect up to 1 in 100 people)
- shaking, tremor or feeling dizzy
- dry mouth, or mild irritation in the throat
- bruising of the skin
- feeling restless, nervous or agitated
- depression
- fast heart beat or uneven heart beat
- chest pain or tightening in the chest (angina pectoris)
- difficulties passing urine

Very rare (may affect up to 1 in 10,000 people)
- changes in behaviour
- an effect on the adrenal gland

Not known (frequency cannot be estimated from the available data):
- blurred vision
- clouding of the lens of your eyes (signs of cataract)
- increased pressure in the eye (glaucoma)
- swelling of your face, particularly around your mouth (swelling of your tongue or throat may make it difficult to swallow)

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 website: www.mhra.gov.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 Trixeo Aerosphere

Keep this medicine out of the sight and reach of children.

Do not use Trixeo Aerosphere after the expiry date which is stated on the carton, pouch and pressurised container after 'EXP'. The expiry date refers to the last day of that month.

After opening the pouch, the inhaler must be used within 3 months.

Keep the inhaler inside the sealed pouch – only remove the inhaler from the sealed pouch immediately before first use. On the day the pouch is opened, write the date on the inhaler label in the space provided.

Do not store above 30 °C. Store in a dry place.

For best results, the inhaler should be at room temperature before you use it.

Do not break, puncture or burn the pressurised container, even when apparently empty. Do not use or store near heat or open flames.

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

Each single inhalation provides a delivered dose (the dose leaving the mouthpiece) of 5 micrograms of formoterol fumarate dihydrate, 9 micrograms glycopyrronium bromide equivalent to 7.2 micrograms glycopyrronium and 160 micrograms of budesonide.

This corresponds to a metered dose (i.e. the dose leaving the valve) of 5.3 micrograms of formoterol fumarate dihydrate, glycopyrronium bromide 9.6 micrograms, equivalent to 7.7 micrograms of glycopyrronium, and budesonide 170 micrograms.

The other ingredients are HFO-1234ze(E), 1,2-distearoyl-sn-glycero-3-phosphocholine and calcium chloride.

This medicine contains fluorinated greenhouse gases. Each inhaler contains 9.5 g of HFO-1234ze(E) corresponding to 0.000013 tonne CO_2 equivalent (low global warming potential GWP = 1.37). HFO-1234ze(E) is a propellant that delivers the puffs of this medicine to your lungs.

What Trixeo Aerosphere looks like and contents of the pack
Trixeo Aerosphere is a pressurised inhalation, suspension.

Trixeo Aerosphere comes as a canister with a dose indicator, supplied with a yellow plastic actuator body and mouthpiece. The mouthpiece is covered with a removable grey protective cap.

Trixeo Aerosphere is supplied in a foil pouch that contains a drying packing (desiccant) and packed into a carton.

Trixeo Aerosphere is available in packs containing 1 inhaler with 120 puffs, and in multipacks comprising 3 cartons, each containing 1 inhaler with 120 puffs. Not all pack sizes may be marketed.

Marketing Authorisation Holder

AstraZeneca UK Limited,
1 Francis Crick Avenue,
Cambridge,
CB2 0AA,
UK.

Manufacturer
AstraZeneca Dunkerque Production
224 Avenue de la Dordogne
59640
Dunkerque
France

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RSP 25 0009

Other sources of information

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

Product name	**Trixeo Aerosphere 5 micrograms/7.2 micrograms/160 micrograms pressurised inhalation, suspension**
Reference number	17901/0352

This is a service provided by the Royal National Institute of the Blind.

Read prior to using inhaler

INSTRUCTIONS FOR USE

TRIXEO AEROSPHERE
formoterol fumarate dihydrate/glycopyrronium/budesonide
Pressurised inhalation, suspension
Inhalation use

Please read these instructions carefully.
Your Trixeo Aerosphere (called "inhaler" in this leaflet) may be different from inhalers you have used before.

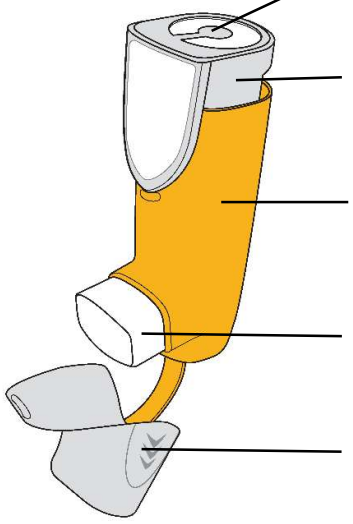
Important information

- **For oral inhalation use only.**
- **Prepare your inhaler for its first time use by priming it.**
- **Rinse your yellow actuator weekly.**
- **Take 2 puffs of medicine in the morning and 2 puffs of medicine in the evening.**

Storing your inhaler

- Do not store above 30 °C. Store in a dry place.
- **Do not store in a humid environment, such as a bathroom.**
- Keep your inhaler and all medicines out of the sight and reach of children.

Parts of your inhaler



Puff indicator
Attached to the top of the pressurised canister.

Pressurised Canister (inside)
Holds the medicine.

Actuator
Contains the pressurised canister.

Mouthpiece
Sprays the medicine.

Mouthpiece cover
Protects the mouthpiece when the inhaler is not in use.

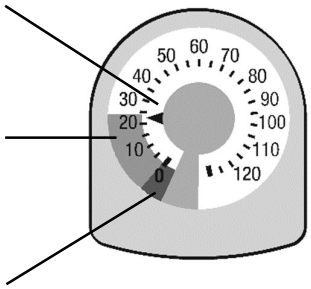
Reading the puff indicator

ⓘ **The puff indicator will count down by 1 each time you spray a puff of medicine.**

Pointer
Points to number of puffs remaining

Yellow zone
Order a new inhaler when the pointer is in the yellow zone

Red zone
Throw away your inhaler when the pointer is at 0 in the red zone



ⓘ **Do not try to take a puff when the pointer is at 0 because you will not receive a full dose.**

Ordering a new inhaler

- Order a new inhaler when the pointer on the puff indicator is in the yellow zone.

Throwing away your inhaler

Throw away your inhaler following local guidelines when:

- puff indicator shows 0

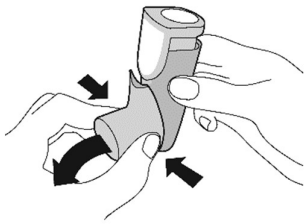
or

- **3 months** after your inhaler has been removed from the foil pouch

Do not reuse or use the actuator with medicine canisters from other inhalers.
Do not puncture or throw the canister into a fire or incinerator.

BEFORE FIRST USE – Prime your inhaler 4 times before first use

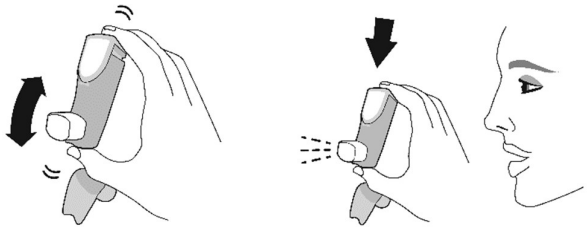
- Before you use your inhaler for the first time, prime it so that you will get the right amount of medicine when you use it.

Prime 1
Remove mouthpiece cover. 

Prime 2

Shake the inhaler well and spray **1 Test-puff** into the air facing away from you. Repeat for a total of **4 Test-puffs**, shaking before each Test-puff.

x4 total
Shake and Test-puffs



ⓘ Extra puffs are provided for priming. **Do not skip priming.**

ⓘ **Re-prime your inhaler:**

- after rinsing the actuator
- if dropped
- if not used for more than 7 days

To re-prime, spray **2 Test-puffs**, shaking before each Test-puff.

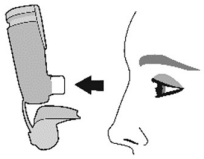
x2 total
Shake and Test-puffs

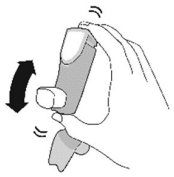
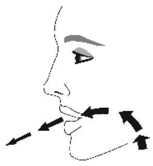
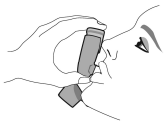
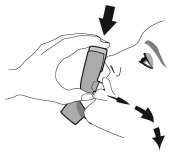
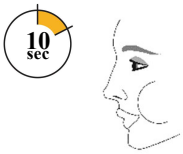
DAILY USE, morning & evening – Inhale your medicine

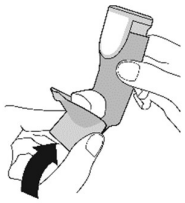
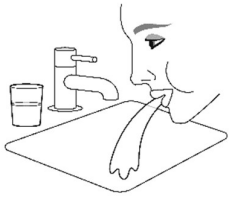
- **Daily Dose: 2 puffs in the morning and 2 puffs in the evening.**
- Rinse mouth with water after the 2 puffs to prevent fungal infection.

Step 1

Remove mouthpiece cover. **Check the mouthpiece for foreign objects and remove objects before use.**

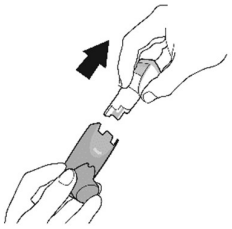
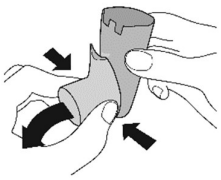


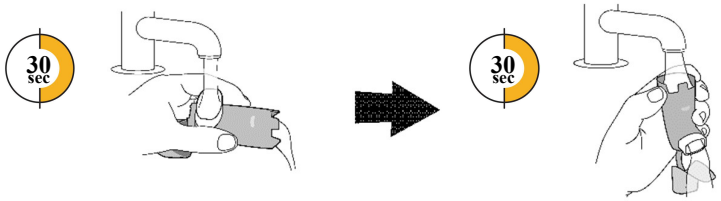
Step 2				
Shake the inhaler well before each puff. 	Breathe out fully. 	Place mouthpiece into mouth and close lips around the mouthpiece. Tilt your head back, keeping your tongue below the mouthpiece. 	Start to breathe in deeply and slowly while spraying **1 puff**. Continue breathing in until you cannot any more. 	Hold breath for as long as you can, up to **10 seconds.** 

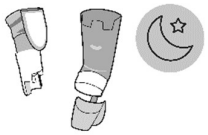
Step 3	Step 4	Step 5
	Put mouthpiece cover back on. 	Rinse mouth with water. Spit out water. **Do not swallow.** 

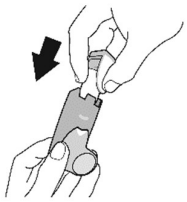
WEEKLY RINSE – Rinse your actuator once a week

- **Rinse yellow actuator weekly** so that medicine does not build up and block the spray through the mouthpiece.
- **Do not allow the canister to get wet.**
- **Re-prime after rinsing.**

Rinse 1	Rinse 2
Remove canister and set aside. **Do not allow the canister to get wet.** 	Remove mouthpiece cover. 

Rinse 3	Rinse 4
Run warm water through the mouthpiece for 30 seconds and then through the top of the actuator for 30 seconds. **Rinse for 60 seconds in total.** 	**Shake off as much water as you can.** **Do not dry with a towel or tissue.**

Rinse 5	Rinse 6
Look into the actuator and mouthpiece for medicine build-up. If there is any build-up, repeat steps Rinse 3 through 5. 	Air-dry, preferably overnight. **Do not** put the canister back into the actuator if it is still wet. 

Rinse 7	Rinse 8
When dry, **replace the mouthpiece cover first** and then gently press the canister down into the actuator. 	Re-prime the inhaler by spraying **2 Test-puffs,** shaking before each Test-puff. **x2 total Shake and Test-puffs**