

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)

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:

- 6 weeks – for an inhaler that contains 56 puffs
- 3 months – for an inhaler than contains 120 puffs.

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.

The other ingredients are norflurane, 1,2- distearoyl-sn-glycero-3-phosphocholine and calcium chloride.

What Trixeo Aerosphere looks like and contents of the pack

Trixeo Aerosphere is a pressurised inhalation, suspension.

Trixeo Aerosphere comes as a pressurised container with a dose indicator, supplied with a white plastic actuator body and mouthpiece (see Figure 1 of the Instructions for Use at the end of this

leaflet). 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.

Each inhaler contains 56 or 120 puffs. Additionally, there are multipacks containing 3 pressurised containers with 120 puffs, each.

Marketing Authorisation Holder

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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.

Instructions for Use
Trixeo Aerosphere 5/7.2/160 micrograms pressurised inhalation, suspension
(formoterol fumarate dihydrate/glycopyrronium/budesonide)
Inhalation use

Read these instructions for use and the package leaflet before you start using Trixeo Aerosphere and each time you get a new pack. There may be new information. As well as reading this leaflet, please talk to your doctor about your medical condition and treatment.

Important Information:

- **For inhalation use only.**
- Use Trixeo Aerosphere exactly as your doctor tells you to.
- If you have any questions about the use of your inhaler, ask your doctor or pharmacist.
- **Clean your inhaler once each week.** It is very important to keep the plastic actuator clean so that medicine does not build-up and block the spray through the mouthpiece. See Steps 1 to 8 under “**How to clean your Trixeo Aerosphere inhaler**”.

Parts of your Trixeo Aerosphere inhaler (See Figure 1):

- Trixeo Aerosphere comes as a pressurised container with a dose indicator that fits into an actuator.
 - **Do not** use the Trixeo Aerosphere actuator with any other medicine.
 - **Do not** use the Trixeo Aerosphere pressurised container with an actuator from any other inhaler.

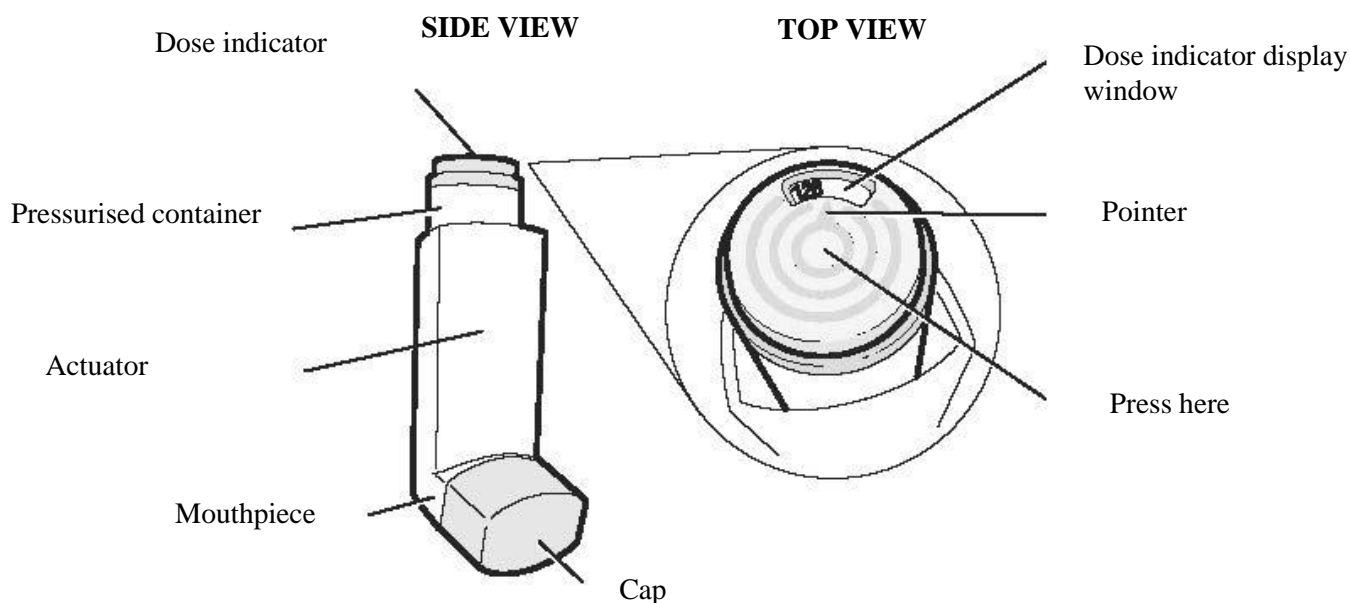


Figure 1

- Trixeo Aerosphere comes with a dose indicator on the top of the pressurised container (see **Figure 1**). The dose indicator display window shows you how many puffs of medicine you have left. A puff of medicine is released each time you press the centre of the dose indicator.

Trixeo Aerosphere pressurised canister contains extra puffs to allow for priming. The step-by-step instructions for use of the inhaler provided below can be used for either the 14-day (56 puffs) or 30-day inhaler (120 puffs).

Before you use Trixeo Aerosphere for the first time

Before you use Trixeo Aerosphere for the first time, make sure that the pointer on the dose indicator is pointing to the right of the “120” inhalation mark in the dose indicator display window (see **Figure 1**).

- The pointer points to 120 after 10 puffs are delivered from Trixeo Aerosphere. This means that there are 120 puffs of medicine left in the pressurised container (see **Figure 2a**).
- The pointer points between 100 and 120 after you use 10 more puffs. This means that there are 110 puffs of medicine left in the pressurised container (see **Figure 2b**).
- The pointer points to 100 after you use 10 more puffs. This means that there are 100 puffs of medicine left in the pressurised container (see **Figure 2c**).



Figure 2a
120 puffs



Figure 2b
110 puffs



Figure 2c
100 puffs

- The dose indicator display window will move after every 10 puffs. The number in the dose indicator display window will change after every 20 puffs.

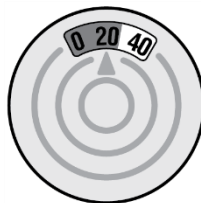


Figure 2d

- The colour in the dose indicator display window will change to red, as shown in the shaded area, when there are only 20 puffs of medicine left in your inhaler (see **Figure 2d**).
- The dose indicator for the 14-day inhaler, 56 inhalation pressurised container, moves after every 10 puffs; with markings for 60, 40, 20 and 0 puffs. The colour in the 14-day inhaler, 56 inhalation pressurised container dose indicator display window will change to red when there are only 20 puffs of medicine left in your inhaler.

Preparing your Trixeo Aerosphere inhaler for use:

- Your Trixeo Aerosphere inhaler comes in a foil pouch that contains a drying packet (desiccant).
 - Take the Trixeo Aerosphere inhaler out of the foil pouch.
 - Throw away the pouch and the drying packet. **Do not** eat or breathe in the contents of the drying packet.
- Trixeo Aerosphere should be at room temperature before you use it.

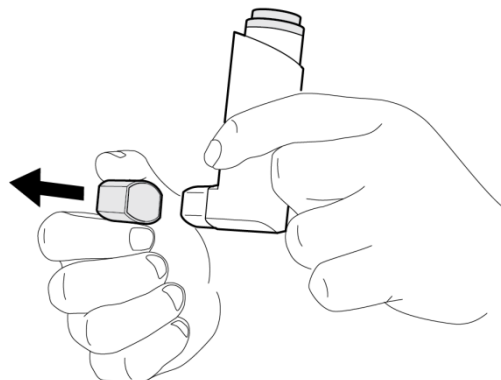


Figure 3

Priming your Trixeo Aerosphere inhaler:

Before you use Trixeo Aerosphere for the first time, you must prime the inhaler.

- Remove the cap from the mouthpiece (see **Figure 3**). Check inside the mouthpiece before you use the inhaler to make sure it is clear.
- Hold the inhaler upright, away from your face and shake it well (see **Figure 4**).

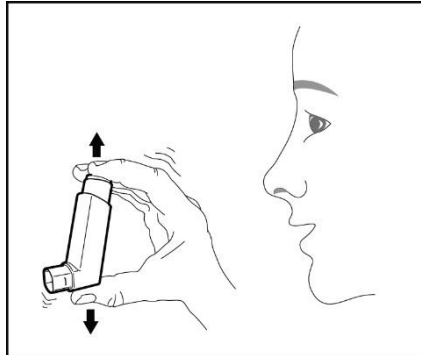


Figure 4

- Press down firmly on the centre of the dose indicator until the pressurised container cannot be pressed any further. This will release a puff of medicine from the mouthpiece (see **Figure 5**). You may hear a soft click from the dose indicator as it counts down during use.

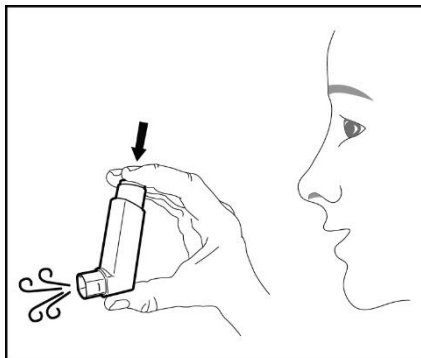


Figure 5

- **Repeat the priming steps 3 more times (see Figure 4 and Figure 5).** Shake the inhaler well before each priming puff.
- After priming 4 times, the dose indicator should be pointing to the right of “120” and your inhaler is now ready to use.

Using your Trixeo Aerosphere inhaler:

Step 1: Remove the cap from the mouthpiece (See **Figure 6**).

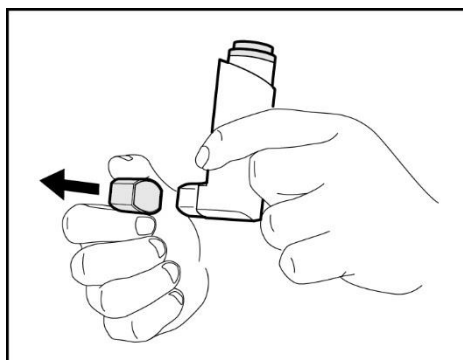


Figure 6

Step 2: Shake the inhaler well before each use (see **Figure 7**).

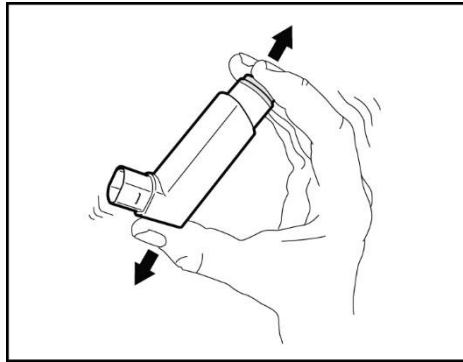


Figure 7

Step 3: Hold the inhaler with the mouthpiece pointing towards you and breathe out as fully as you comfortably can through your mouth (see **Figure 8**).

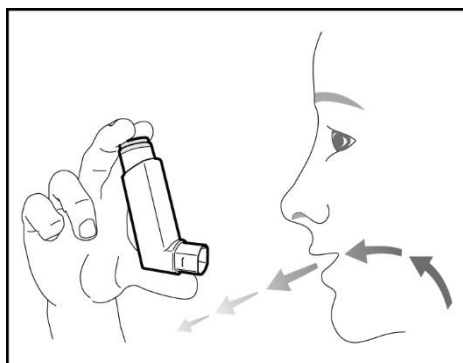


Figure 8

Step 4: Close your lips around the mouthpiece and tilt your head back, keeping your tongue below the mouthpiece (see **Figure 9**).

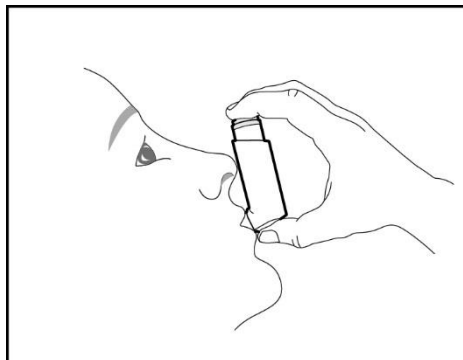


Figure 9

Step 5: While breathing in deeply and slowly, press down on the centre of the dose indicator as far as the pressurised container will go and a puff of medicine has been released (see **Figure 10**). Then stop pressing the dose indicator.

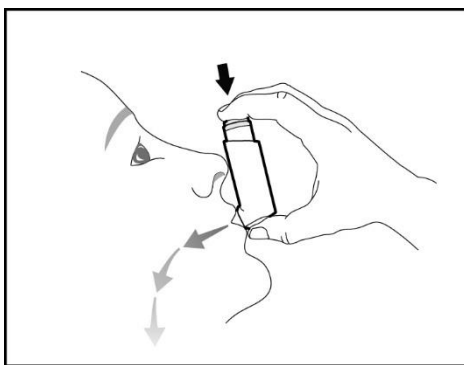


Figure 10

Step 6: When you have finished breathing in, remove the mouthpiece from your mouth. Hold your breath as long as you comfortably can, up to 10 seconds (see **Figure 11**).

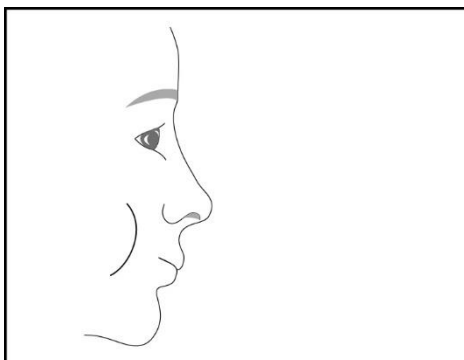


Figure 11

Step 7: Breathe out gently (see **Figure 12**). Repeat steps 2 to 7 to take your second puff of Trixeo Aerosphere.

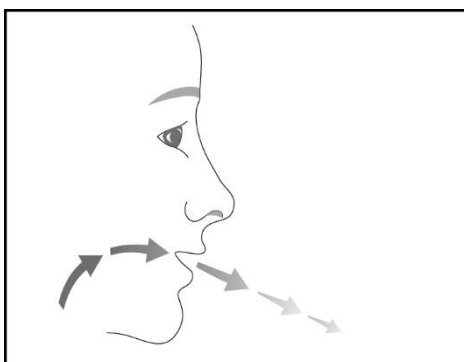


Figure 12

Step 8: Replace the cap over the mouthpiece right away after use (see **Figure 13**).

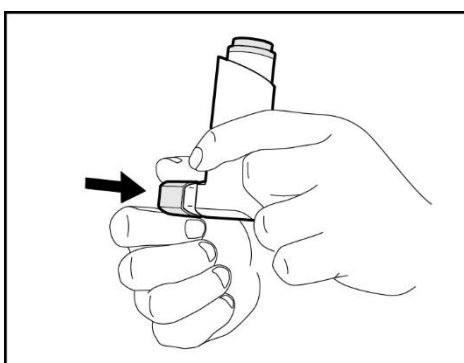


Figure 13

Step 9: Rinse your mouth with water to remove any medicine which is left in the mouth. Spit this water out – **do not** swallow.

It is important to store Trixeo Aerosphere in a dry place.

How to clean your Trixeo Aerosphere inhaler:

Clean the inhaler once each week. It is very important to keep your inhaler clean so that medicine does not build-up and block the spray through the mouthpiece (see **Figure 14**).

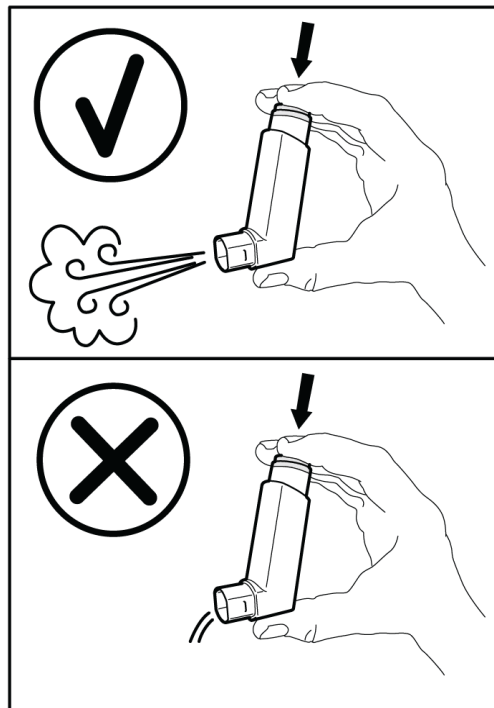


Figure 14

Step 1: Take the pressurised container out of the actuator (see **Figure 15**). **Do not** clean the pressurised container or let it get wet.

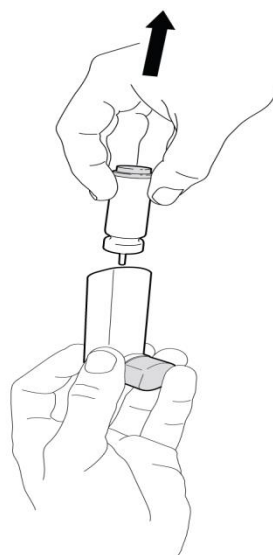


Figure 15

Step 2: Take the cap off the mouthpiece.

Step 3: Hold the actuator under the tap and run warm water through it for about 30 seconds. Turn the actuator upside down and run warm water through it again for about 30 seconds (see **Figure 16**).

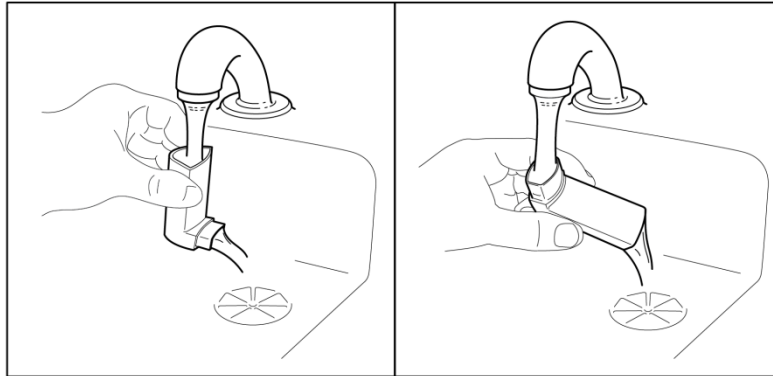


Figure 16

Step 4: Shake off as much water from the actuator as you can.

Step 5: Look into the actuator and the mouthpiece to make sure any medicine build-up has been completely washed away. If there is any build-up, **repeat Steps 3 to 5** in this section.

Step 6: Let the actuator air-dry overnight (see **Figure 17**). **Do not** put the pressurised container back into the actuator if it is still wet.

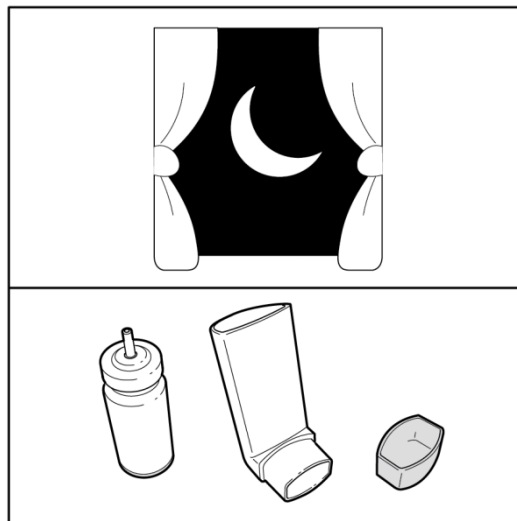


Figure 17

Step 7: When the actuator is dry, gently press the pressurised container down in the actuator (see **Figure 18**). **Do not** press down too hard on the pressurised container. This could cause a puff of medicine to be released.

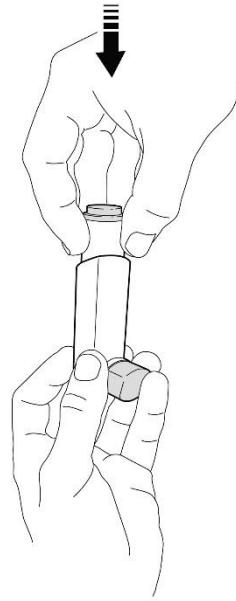


Figure 18

Step 8: Re-prime your Triexo Aerosphere inhaler after each cleaning. To re-prime the inhaler, shake the inhaler well and press down on the centre of the dose indicator 2 times to release a total of 2 puffs into the air away from your face. Your inhaler is now ready to use.

If you do not use your Triexo Aerosphere for more than 7 days, or your Triexo Aerosphere is dropped, you will need to re-prime it before use.

To re-prime the inhaler, shake the inhaler well and press down on the centre of the dose indicator 2 times to release a total of 2 puffs into the air away from your face. Your inhaler is now ready to use.