

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

INTERMEDIATE OUTER CARTON (WITHOUT BLUE BOX- MULTIPACK ONLY)

1. NAME OF THE MEDICINAL PRODUCT

Temybric Ellipta 92 micrograms/55 micrograms/22 micrograms inhalation powder, pre-dispensed fluticasone furoate/umeclidinium/vilanterol

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each delivered dose contains 92 micrograms of fluticasone furoate, 55 micrograms of umeclidinium (equivalent to 65 micrograms umeclidinium bromide) and 22 micrograms of vilanterol (as trifenate).

3. LIST OF EXCIPIENTS

Excipients: lactose and magnesium stearate.
See package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Inhalation powder, pre-dispensed
1 inhaler of 30 doses.
Component of a multipack, can't be sold separately.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

ONCE DAILY

Read the package leaflet before use.
Inhalation use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP
In use shelf-life: 6 weeks.
Discard by:

9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C
Store in the original package in order to protect from moisture.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

GlaxoSmithKline Trading Services Limited
12 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

12. MARKETING AUTHORISATION NUMBER(S)

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

temybric ellipta

17. UNIQUE IDENTIFIER – 2D BARCODE

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

TRAY LABEL

1. NAME OF THE MEDICINAL PRODUCT

Temybric Ellipta 92/55/22 mcg inhalation powder
fluticasone furoate/umeclidinium/vilanterol

2. NAME OF THE MARKETING AUTHORISATION HOLDER

GlaxoSmithKline Trading Services Limited
GSK Logo

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

Do not open until ready to inhale.
In use shelf-life: 6 weeks.

14 doses
30 doses

Medicinal product no longer authorised

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

INHALER LABEL

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Temybric Ellipta 92 /55 /22 mcg inhalation powder
fluticasone furoate/umeclidinium/vilanterol
Inhalation use

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

EXP

In use shelf-life: 6 weeks.
Discard by:

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

14 doses
30 doses

6. OTHER

Medicinal product no longer authorised

Medicinal product no longer authorised

B. PACKAGE LEAFLET

Package leaflet: Information for the patient

Temybric Ellipta 92 micrograms/55 micrograms/22 micrograms inhalation powder, pre-dispensed fluticasone furoate/umeclidinium/vilanterol

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Temybric Ellipta is and what it is used for
 2. What you need to know before you use Temybric Ellipta
 3. How to use Temybric Ellipta
 4. Possible side effects
 5. How to store Temybric Ellipta
 6. Contents of the pack and other information
- Step-by-step instructions

1. What Temybric Ellipta is and what it is used for

What Temybric Ellipta is

Temybric Ellipta contains three active substances called fluticasone furoate, umeclidinium bromide and vilanterol. Fluticasone furoate belongs to a group of medicines called corticosteroids, often simply called steroids. Umeclidinium bromide and vilanterol belong to a group of medicines called bronchodilators.

What Temybric Ellipta is used for

Temybric Ellipta is used to treat chronic obstructive pulmonary disease (**COPD**) in adults. COPD is a long-term condition characterised by breathing difficulties that slowly get worse.

In COPD the muscles around the airways tighten, making breathing difficult. This medicine widens these muscles in the lungs, reducing the swelling and irritation in the small air passages and making it easier for air to get in and out of the lungs. When used regularly, it can help to control your breathing difficulties and reduce the effects of COPD on your everyday life.

Temybric Ellipta should be used every day and not only when you have breathing problems or other symptoms of COPD. It should not be used to relieve a sudden attack of breathlessness or wheezing. If you get this sort of attack you must use a quick-acting inhaler (such as salbutamol). If you do not have a quick-acting inhaler contact your doctor.

2. What you need to know before you use Temybric Ellipta

Don't use Temybric Ellipta:

- if you are allergic to fluticasone furoate, umeclidinium, vilanterol or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor before using Temybric Ellipta

- if you have **asthma** (Don't use Temybric Ellipta to treat asthma)
- if you have **heart problems** or **high blood pressure**
- if you have **liver problems**
- if you have **tuberculosis (TB) of the lung**, or **any long standing or untreated infections**
- if you have an eye problem called **narrow-angle glaucoma**
- if you have an **enlarged prostate, difficulty passing urine** or a **blocking in your bladder**
- if you suffer from **epilepsy**
- if you have **thyroid gland problems**
- if you have **low potassium** in your blood
- if you have a history of **diabetes**
- if you experience blurred vision or other **visual disturbances**

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

Immediate breathing difficulties

If you get tightness of the chest, coughing, wheezing or breathlessness immediately after using your Temybric Ellipta inhaler:

Stop using this medicine and seek medical help immediately, as you may have a serious condition called paradoxical bronchospasm.

Eye problems during treatment with Temybric Ellipta

If you get eye pain or discomfort, temporary blurring of vision, visual halos or coloured images as well as red eyes during treatment with Temybric Ellipta.

Stop using this medicine and seek medical help immediately, these may be signs of an acute attack of narrow-angle glaucoma.

Infection of the lung

Because you are using this medicine for COPD, you may be at an increased risk of developing an infection of the lungs known as pneumonia. See section 4 'Possible side effects' for information on symptoms to look out for while you are using this medicine.

Tell your doctor as soon as possible if you develop any of these symptoms.

Children and adolescents

Do not give this medicine to children or adolescents below the age of 18 years.

Other medicines and Temybric Ellipta

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. If you are not sure what your medicine contains talk to your doctor or pharmacist.

Some medicines may affect how this medicine works, or make it more likely that you'll have side effects. These include:

- medicines called beta blockers (such as propranolol), to treat high blood pressure or other heart problems
- ketoconazole or itraconazole, to treat fungal infections

- clarithromycin or telithromycin, to treat bacterial infections
- ritonavir or cobicistat, to treat HIV infection
- medicines that lower the amount of potassium in your blood, such as some diuretics (water tablets) or some medicines used to treat COPD and asthma (such as methylxanthine or steroids)
- other long-acting medicines similar to this medicine that are used to treat breathing problems, e.g. tiotropium, indacaterol. Don't use Temybric Ellipta if you already use these medicines.

Tell your doctor or pharmacist if you are taking any of these. Your doctor may wish to monitor you carefully if you are taking any of these medicines as they may increase the side effects of Temybric Ellipta.

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 for advice before taking this medicine. Don't use this medicine if you are pregnant unless your doctor tells you that you can.

It is not known whether the ingredients of this medicine can pass into breast milk. If you are breast-feeding, you must check with your doctor before you use Temybric Ellipta. Don't 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.

Temybric Ellipta contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using this medicine.

3. How to use Temybric Ellipta

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

The **recommended dose** is one inhalation every day at the same time of day. You only need to inhale once a day because the effect of this medicine lasts for 24 hours.

Don't use more than your doctor tells you to use.

Use Temybric Ellipta regularly

It is very important that you use Temybric Ellipta every day, as instructed by your doctor. This will help to keep you free of symptoms throughout the day and night.

Temybric Ellipta should **not** be used to relieve a **sudden attack of breathlessness or wheezing**. If you get this sort of attack you must use a quick-acting reliever inhaler (such as salbutamol).

How to use the inhaler

See '*Step-by-step instructions*' in this leaflet for full information.

Temybric Ellipta is for inhalation use.

Once the tray is opened Temybric Ellipta is ready to use.

If your symptoms do not improve

If your COPD symptoms (breathlessness, wheezing, cough) do not improve or get worse, or if you are using your quick-acting inhaler more often:

contact your doctor as soon as possible.

If you use more Temybric Ellipta than you should

If you use too much of this medicine, **contact your doctor or pharmacist for advice immediately** as you may need medical attention. If possible, show them the inhaler, the package or this leaflet. You may notice that your heart is beating faster than usual, you feel shaky, you have visual disturbances, have a dry mouth, or have a headache.

If you forget to use Temybric Ellipta

Don't inhale a double dose to make up for a forgotten dose. Just inhale your next dose at the usual time. If you become wheezy or breathless, use your quick-acting inhaler (such as salbutamol), then seek medical advice.

If you stop using Temybric Ellipta

Use this medicine for as long as your doctor recommends. Don't stop unless your doctor advises you to, even if you feel better, as your symptoms may get worse.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Allergic reactions

Allergic reactions to Temybric Ellipta are rare (they may affect up to 1 in 1,000 people).

If you have any of the following symptoms after taking Temybric Ellipta, **stop using it and tell your doctor immediately**:

- skin rash or redness, hives (*urticaria*)
- swelling, sometimes of the face or mouth (*angioedema*)
- wheezing, coughing or having difficulty in breathing
- suddenly feeling weak or light headed (may lead to collapse or loss of consciousness)

Immediate breathing difficulties

If your breathing or wheezing gets worse straight after using this medicine, **stop using it and get medical help immediately**.

Pneumonia (infection of the lung) in COPD patients (common side effect)

Tell your doctor if you have any of the following while using Temybric Ellipta – these could be symptoms of a lung infection:

- fever or chills
- increased mucus production, change in mucus colour
- increased cough or increased breathing difficulties

Common side effects

These may affect **up to 1 in 10** people:

- sore, raised patches in the mouth or throat caused by a fungal infection (candidiasis). Rinsing your mouth out with water immediately after using Temybric Ellipta may help prevent this side effect.
- infection of the nose, sinuses or throat
- infection of the upper airways
- itchy, runny or blocked nose
- pain in the back of the mouth and throat
- inflammation of the sinuses
- inflammation of the lungs (*bronchitis*)
- flu (*influenza*)
- common cold
- headache
- cough

- painful and frequent urination (may be signs of a urinary tract infection)
- joint pain
- back pain
- constipation.

Uncommon side effects

These may affect **up to 1 in 100** people:

- irregular heart beat
- faster heart beat
- hoarseness
- weakening of the bones, leading to fractures
- dry mouth
- taste disturbance
- blurred vision
- increased eye pressure
- eye pain.

Rare side effects

These may affect **up to 1 in 1,000** people:

- allergic reactions (see earlier in Section 4)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Temybric Ellipta

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

Don't use this medicine after the expiry date which is stated on the carton, tray and inhaler after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 30°C.

Keep the inhaler inside the sealed tray in order to protect from moisture and only remove immediately before first use. Once the tray is opened, the inhaler can be used for up to 6 weeks, starting from the date of opening the tray. Write the date the inhaler should be thrown away on the label in the space provided. The date should be added as soon as the inhaler has been removed from the tray.

If stored in a refrigerator, allow the inhaler to return to room temperature for at least one hour before use.

Do not throw away any medicines via household waste. Ask your pharmacist how to dispose of medicines no longer required. This will help to protect the environment.

6. Contents of the pack and other information

What Temybric Ellipta contains

The active substances are fluticasone furoate, umeclidinium bromide and vilanterol.

Each single inhalation provides a delivered dose (the dose leaving the mouthpiece) of 92 micrograms of fluticasone furoate, 65 micrograms umeclidinium bromide equivalent to 55 micrograms umeclidinium and 22 micrograms of vilanterol (as trifenate).

The other ingredients are lactose monohydrate (see section 2 under ‘Temybric Ellipta contains lactose’) and magnesium stearate.

What Temybric Ellipta looks like and contents of the pack

Temybric Ellipta is an inhalation powder, pre-dispensed.

The Ellipta inhaler consists of a light grey plastic body, a beige coloured mouthpiece cover and a dose counter. It is packaged in a foil laminate tray with a peelable foil lid. The tray contains a desiccant sachet, to reduce moisture in the packaging.

The active substances are present as a white powder in separate blister strips inside the inhaler. Each inhaler contains either 14 or 30 doses (14 or 30 day supply). Multipacks containing 90 (3 inhalers of 30) doses (90 day supply) are also available. Not all pack sizes may be marketed in your country.

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>.

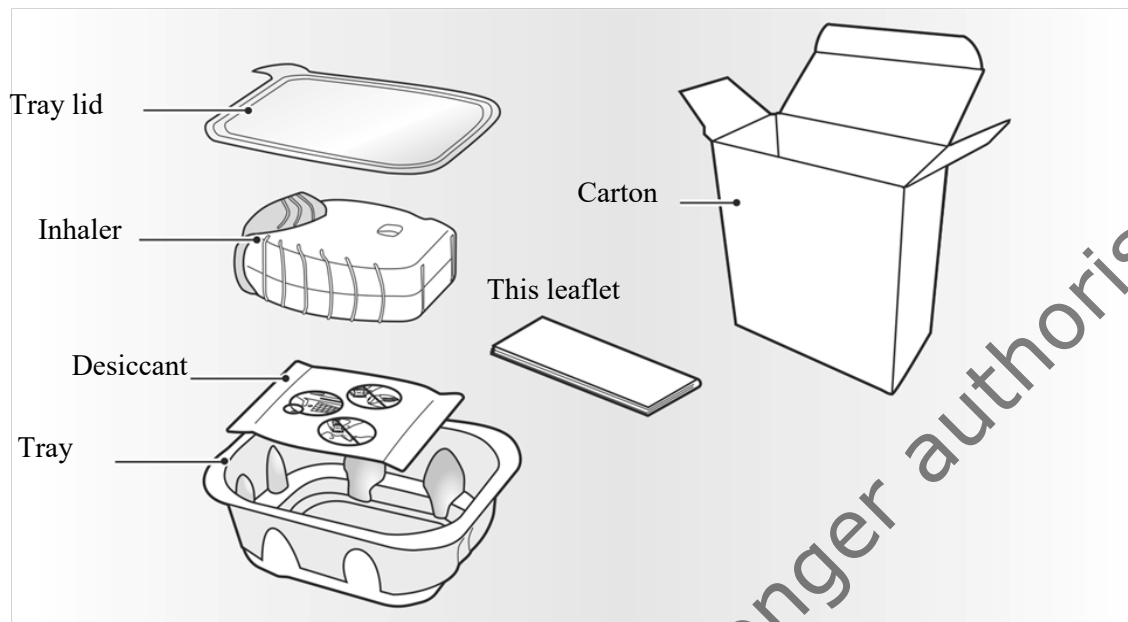
Medicinal product no longer authorised

Step-by-step instructions

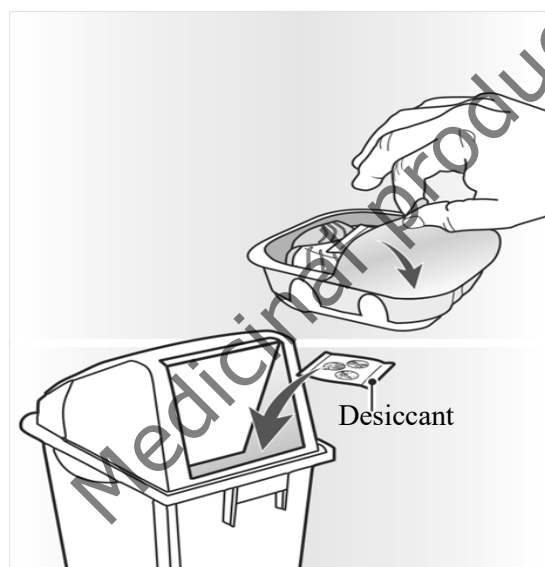
What is the inhaler?

The first time you use Temybric Ellipta you do not need to check that the inhaler is working properly; it contains previously measured doses and is ready to use straight away.

Your Temybric Ellipta inhaler carton contains



The inhaler is packaged in a tray. **Do not open the tray until you are ready to inhale a dose of your medicine.** When you are ready to use your inhaler, peel back the lid to open the tray. The tray contains a desiccant sachet, to reduce moisture. Throw this desiccant sachet away — **don't** open, eat or inhale it.



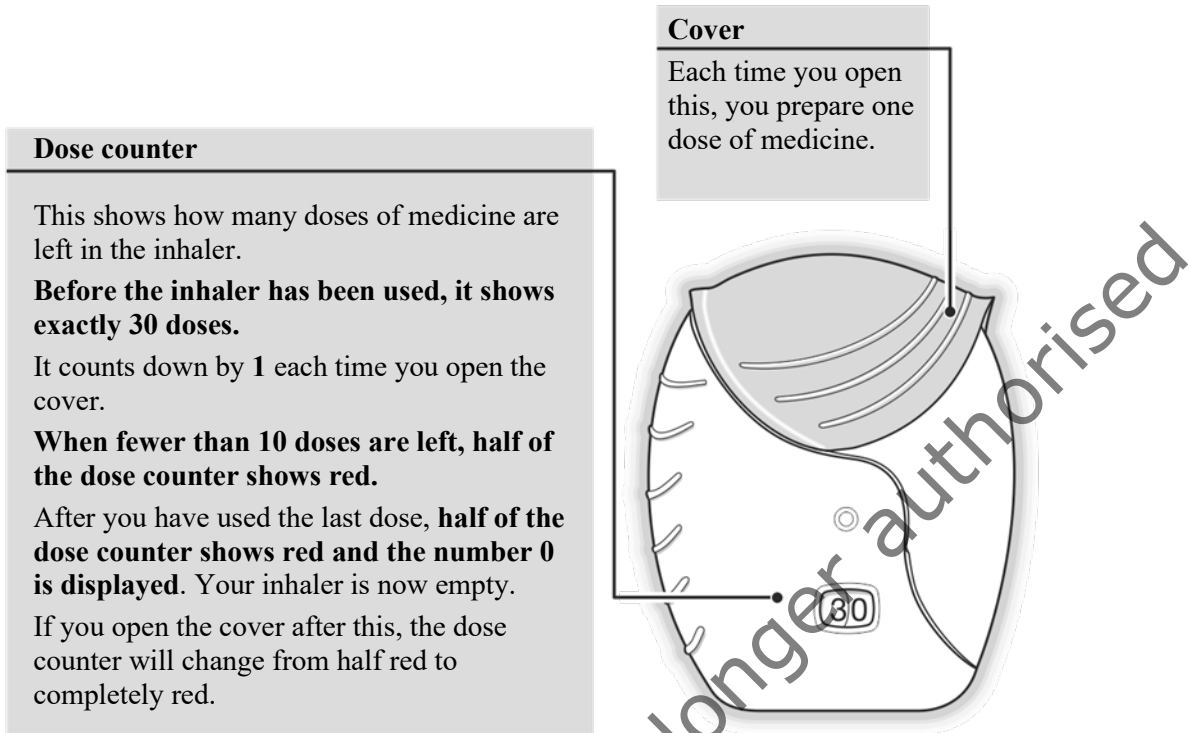
When you take the inhaler out of the sealed tray, it will be in the 'closed' position. **Don't open the inhaler until you are ready to inhale a dose of medicine.** Write the "Discard by" date on the inhaler label and the carton in the space provided. The "Discard by" date is 6 weeks from the date you open the tray. **After this date the inhaler should no longer be used.** The tray can be discarded after first opening.

The step-by-step instructions for use of the inhaler provided below can be used for either the 30-dose (30 day supply) or the 14-dose (14 day supply) Ellipta inhaler.

1) Read this before you start

If you open and close the cover without inhaling the medicine, you will lose the dose.

The lost dose will be securely held inside the inhaler, but it will no longer be available. It is not possible to accidentally take extra medicine or a double dose in one inhalation.



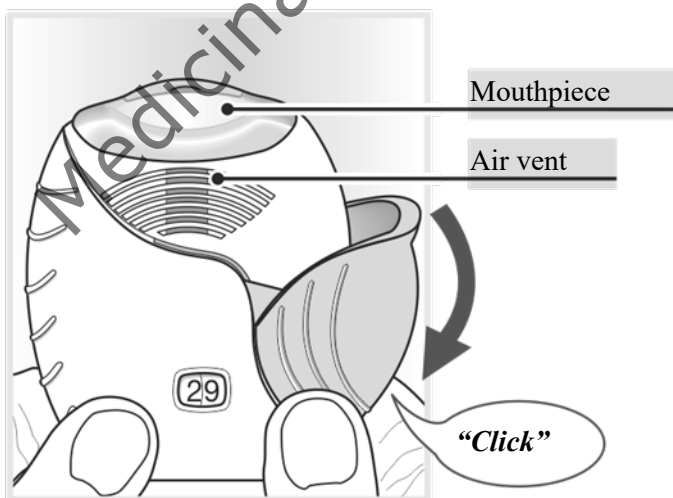
For the 14-dose inhaler, the dose counter will also show half red when there are fewer than 10 doses left, and then will show half red with the number 0 after the last dose is used. The dose counter will appear completely red if the cover is opened again.

2) Prepare a dose

Wait to open the cover until you are ready to take your dose.

Do not shake the inhaler.

- **Slide the cover down until you hear a “click”.**



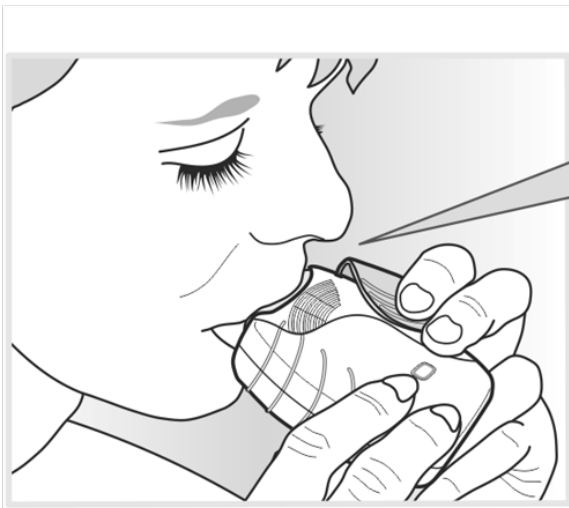
Your medicine is now ready to be inhaled.

The dose counter counts down by 1 to confirm.

- **If the dose counter does not count down as you hear the “click”, the inhaler will not deliver medicine.** Take it back to your pharmacist for advice.
- **Don’t shake the inhaler at any time.**

3) Inhale your medicine

- **While holding the inhaler away from your mouth, breathe out as far as is comfortable. Don’t breathe out into the inhaler.**
- **Put the mouthpiece between your lips, and close your lips firmly around it. Don’t block the air vent with your fingers.**



Your lips fit over the contoured shape of the mouthpiece for inhaling. Don't block the air vent with your fingers.

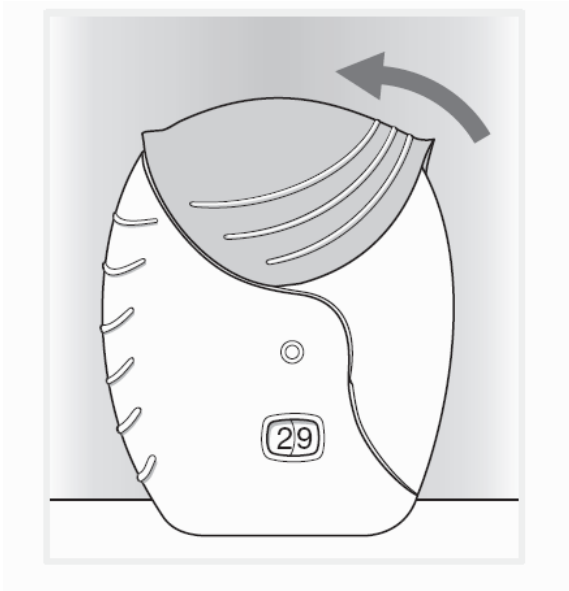
- Take one long, steady, deep breath in. Hold this breath in for as long as possible (at least 3-4 seconds).
- Remove the inhaler from your mouth.
- Breathe out slowly and gently.

You may not be able to taste or feel the medicine, even when you are using the inhaler correctly.

If you want to clean the mouthpiece, use a **dry tissue**, **before** you close the cover.

4) Close the inhaler and rinse your mouth

- **Slide the cover upwards as far as it will go, to cover the mouthpiece.**



- **Rinse your mouth with water after you have used the inhaler, do not swallow.**
This will make it less likely that you will develop a sore mouth or throat as side effects.

Medicinal product no longer authorised