Package leaflet: Information for the user

Relvar® Ellipta® 92 micrograms/22 micrograms inhalation powder, pre-dispensed
Relvar® Ellipta® 184 micrograms/22 micrograms inhalation powder, pre-dispensed

Fluticasone furoate/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 taking 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 Relvar Ellipta is and what it is used for

Relvar Ellipta contains two active substances: fluticasone furoate and vilanterol. Two different strengths of Relvar Ellipta are available: fluticasone furoate 92 micrograms/vilanterol 22 micrograms and fluticasone furoate 184 micrograms/vilanterol 22 micrograms.

The 92/22 micrograms strength is used for the regular treatment of chronic obstructive pulmonary disease (**COPD**) in adults, and **asthma** in adults and adolescents 12 years and over.

The 184/22 micrograms strength is used to treat **asthma** in adults and adolescents aged 12 years and older.

> **Relvar Ellipta should be used every day and not only when you have breathing problems or other symptoms of COPD and asthma. 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).

Fluticasone furoate belongs to a group of medicines called corticosteroids, often simply called steroids. Corticosteroids reduce inflammation. They reduce the swelling and irritation in the small air passages in the lungs and so gradually ease breathing problems. Corticosteroids also help to prevent attacks of asthma and aggravation of COPD.

Vilanterol belongs to a group of medicines called long acting bronchodilators. It relaxes the muscles of the small air passages in the lungs. This helps to open the airways and makes it easier for air to get in and out of the lungs. When it is taken regularly, it helps the small air passages to remain open.

When you take these two active substances together regularly, they will help to control your breathing difficulties more than either medicine alone.

Asthma is a serious, long term lung disease where the muscles surrounding the smaller airways become tight (*bronchoconstriction*) and swollen and irritated (*inflammation*). Symptoms come and go and include shortness of breath, wheezing, chest tightness and cough.

Chronic obstructive pulmonary disease (COPD) is a serious, long term lung disease where the airways become inflamed and thickened. Symptoms include shortness of breath, cough, chest discomfort and coughing up mucus. Relvar Ellipta has been shown to reduce flare-ups of COPD symptoms.

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

Do not use Relvar Ellipta
- if you are **allergic** to fluticasone furoate, vilanterol or any other ingredients of this medicine (listed in section 6).
- if you think the above applies to you, **don't use Relvar Ellipta** until you have checked with your doctor.

Take special care with Relvar Ellipta
Talk to your doctor before you use Relvar Ellipta:
- if you have **liver disease**, as you may be more likely to have side effects. If you have moderate or severe liver disease, your doctor will limit your dose to the lower strength of Relvar Ellipta (92/22 micrograms once daily).
- if you have **heart problems** or **high blood pressure**.
- if you have tuberculosis (TB) of the lung, or any long standing or untreated infections.
- if you have a history of diabetes.
- if you have **thyroid gland problems**.
- if you have **low potassium** in your blood.

Check with your doctor before you use this medicine if you think any of these applies to you.

Immediate breathing difficulties
If your breathing or wheezing gets worse straight after using Relvar Ellipta, **stop using it** and **get medical help** immediately.

Infection of the lung
If 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
This medicine is not recommended in children under the age of 12 years for the treatment of asthma, or in children and adolescents of any age for the treatment of COPD.

Other medicines and Relvar Ellipta
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines may affect how this medicine works, or make it more likely that you will have side effects. These include:
- beta-blockers, such as metoprolol, used to treat **high blood pressure** or **a heart condition.**
- ketoconazole, to treat **fungal infections**.

- ritonavir, to treat **HIV infections.**
- long-acting beta$_2$-adrenergic agonists, such as salmeterol

Tell your doctor or pharmacist if you are taking any of these medicines.

Pregnancy
Relvar Ellipta should only be considered for pregnant women if the expected benefits outweigh the risks.
If you are pregnant, if you think you may be pregnant, or if you are planning to have a baby, ask your doctor for advice before taking this medicine.

Breast-feeding
It is not known whether this medicine can pass into breast milk. Therefore a risk to breastfed infants cannot be ruled out.

If you are breast-feeding, **check with your doctor** before you take Relvar Ellipta.

Driving and using machines
This medicine is unlikely to affect your ability to drive or use machines.

Relvar Ellipta contains lactose
If you have been diagnosed with an intolerance to some sugars, or to milk protein, talk to your doctor before you use this medicine.

3. How to use Relvar Ellipta

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

How much to use

Asthma
The recommended dose to treat asthma is one inhalation (92 micrograms of fluticasone furoate and 22 micrograms of vilanterol) once daily at the same time each day.

If you have severe asthma, your doctor may decide that you should use one inhalation of the higher strength inhaler (184 micrograms fluticasone furoate and 22 micrograms of vilanterol). This dose is also used once daily at the same time each day.

COPD
The recommended dose to treat COPD is one inhalation (92 micrograms of fluticasone furoate and 22 micrograms of vilanterol) once daily at the same time each day.

The higher strength of Relvar Ellipta is not suitable for the treatment of COPD.

Use Relvar Ellipta at the same time each day as it is effective over 24 hours
It is very important that you use this medicine every day, as instructed by your doctor. This will help to keep you free of symptoms throughout the day and night.

Relvar 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 inhaler (such as salbutamol).

If you feel you are getting breathless or wheezy more often than normal, or if you are using your quick-acting inhaler more than usual, see your doctor.

How to use Relvar Ellipta
See 'Step-by-step instructions' after section 6 of this leaflet for full information.

You do not need to prepare Relvar Ellipta in any special way, not even the first time you use it.

If your symptoms do not improve
If your 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 Relvar Ellipta than you should
If you accidentally take more Relvar Ellipta than your doctor has instructed, talk to your doctor or pharmacist. You may notice that your heart is beating faster than usual, you feel shaky or have a headache.

If you have used more than instructed for a long period of time, it is particularly important that you ask your doctor or pharmacist for advice. This is because larger doses of Relvar Ellipta may reduce the amount of steroid hormones produced naturally by your body.

If you forget to use Relvar Ellipta
Do not take a double dose to make up for a forgotten dose. Just take your next dose at the usual time.

If you become wheezy or breathless, or develop any other symptoms of an asthma attack, **use your quick-acting inhaler** (e.g. salbutamol), then seek medical advice.

Do not stop using Relvar Ellipta without advice
Use this medicine for as long as your doctor recommends. It will only be effective as long as you are using it. Do not stop unless your doctor advises you to, even if you feel better.

If you have 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 Relvar Ellipta are rare (they affect less than 1 person in 1000).
If you have any of the following symptoms after taking Relvar Ellipta **stop taking this medicine and tell your doctor immediately**.
- skin rash (*hives*) or redness
- swelling, sometimes of the face or mouth (*angioedema*)
- becoming very wheezy, coughing or having difficulty in breathing
- suddenly feeling weak or light headed (which 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.

Infection of the lungs (common side effect)
Tell your doctor if you have any of the following while taking Relvar Ellipta – they could be symptoms of a lung infection:
- fever or chills
- increased mucus production, change in mucus colour
- increased cough or increased breathing difficulties

Other side effects include:

Very common side effects
These may affect **more than 1 in 10** people:
- headache
- common cold

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 Relvar Ellipta may help stop this side effect developing.
- inflammation of the lungs *(bronchitis*)
- infection of the nose sinuses or throat
- flu (*influenza*)
- pain and irritation in the back of the mouth and throat
- inflammation of the sinuses
- itchy, runny or blocked nose
- cough
- voice disorders
- weakening of the bones, leading to fractures
- stomach pain
- back pain
- high temperature (*fever*)
- joint pain
- muscle spasms

Uncommon side effect
This may affect **up to 1 in 100** people:
- irregular heartbeat

Rare side effects
These may affect up to **1 in 1,000** people:
- allergic reactions
- heart beating faster *(tachycardia)*
- awareness of heart beat *(palpitations)*
- tremor
- anxiety

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

Ireland
HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.
Website: www.hpra.ie; E-mail: medsafety@hpra.ie

Malta

ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

5. How to store Relvar Ellipta

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

Do not use this medicine after the expiry date which is stated on the pack after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original package in order to protect from moisture and do not open the foil lid tray until ready to inhale. 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 discarded on the label in the space provided. The date should be added as soon as the inhaler has been removed from the tray.

If you store in a refrigerator, **allow the inhaler to return to room temperature for at least an hour** before use.

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 Relvar Ellipta contains

- The active substances are fluticasone furoate and vilanterol. Each single inhalation provides a delivered dose (the dose leaving the mouthpiece) of 92 or 184 micrograms of fluticasone furoate and 22 micrograms of vilanterol (as trifenatate).
- The other ingredients are lactose monohydrate and magnesium stearate.

What Relvar Ellipta looks like and contents of the pack
Relvar Ellipta is a white powder. The Ellipta device itself is a light grey inhaler with a yellow 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. Once you have opened the lid of the tray, throw the desiccant away – do not eat or inhale it. The device does not need to be stored in the foil laminate tray once it has been opened.

The inhaler contains two aluminium foil laminate strips of 14 or 30 doses. Multipacks contain 3 x 30 dose inhalers.

Step by step instructions

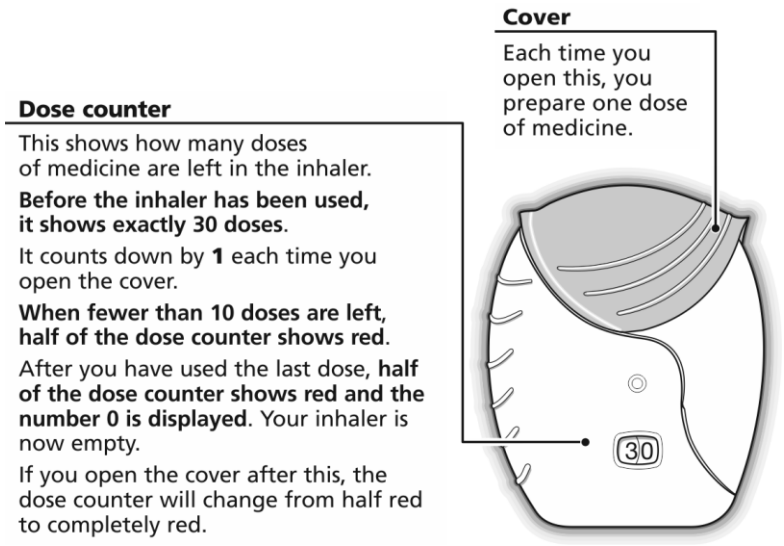
What is the Ellipta inhaler?
When you first use the Ellipta inhaler you do not need to check that it is working properly, and you do not need to prepare it for use in any special way. Just follow these step-by-step instructions.

The inhaler is packaged in a tray containing a desiccant sachet, to reduce moisture. Throw this sachet away – do not eat or inhale it.

When you take the inhaler out of its tray, it will be in the ‘closed’ position. **Do not open it until you are ready to inhale a dose of medicine.** When the tray is opened, write the “Discard by” date on the inhaler label in the space provided. The “Discard by” date is 6 weeks from the date you opened the tray. After this date the inhaler should no longer be used. The tray can be discarded after first opening.

1. Read this before you start

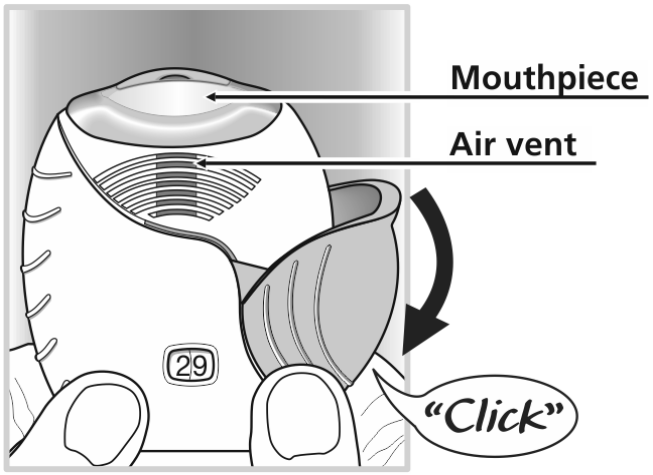
If you open and close the cover without inhaling the medicine, you will lose the dose.
The lost dose will be securely held inside the inhaler, but it will no longer be available.
It is not possible to accidentally take extra medicine or a double dose in one inhalation.



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".**



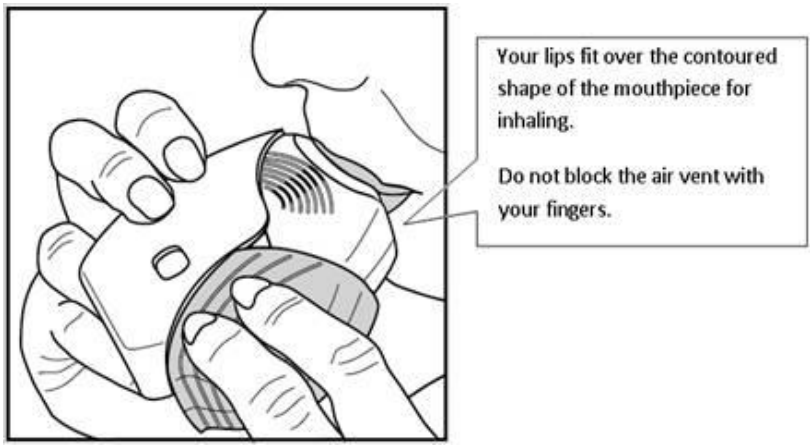
Your medicine is now ready to be inhaled.
The dose counter counts down by **1** to confirm.

- 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.

3. Inhale your medicine

- **While holding the inhaler away from your mouth, breathe out as far as is comfortable.**
  Do not breathe out into the inhaler.

- **Put the mouthpiece between your lips, and close your lips firmly around it.**
  Do not block the air vent with your fingers.



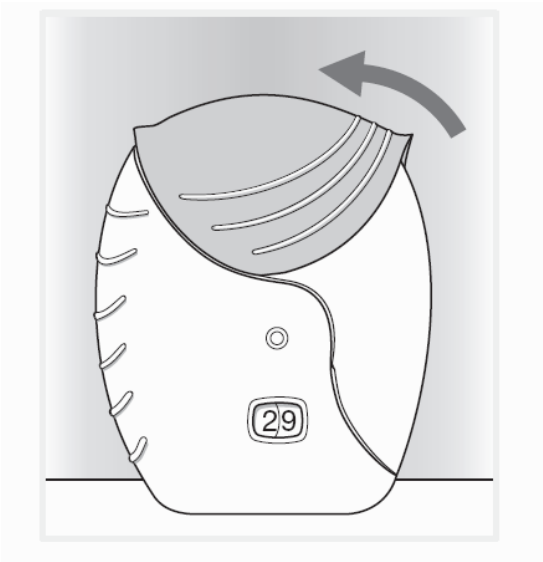
- **Take one long, steady, deep breath in. Hold this breath for as long as possible (at least 3-4 seconds).**
- **Remove the inhaler from your mouth.**
- **Breathe out slowly and gently.**

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

4. Close the inhaler and rinse your mouth if possible

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

- **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.**

This will make it less likely that you will develop a sore mouth or throat as side effects.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

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Middlesex TW8 9GS.
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Manufacturer:

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This leaflet was last revised in January 2016.

Other sources of information

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