

RELVAR ELLIPTA Inhalation Powder, pre-dispensed

Fluticasone furoate/vilanterol (100/25 micrograms and 200/25 micrograms)

What is in this leaflet

1. What Relvar Ellipta is used for
2. How Relvar Ellipta works
3. Before you use Relvar Ellipta
4. How to use Relvar Ellipta
5. While you are using it
6. Side Effects
7. Storage and Disposal of Relvar Ellipta
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision
11. Serial Number

What Relvar Ellipta is used for

The 100/25 micrograms strength is used for the regular treatment of chronic obstructive pulmonary disease (COPD) in adults, and asthma in adults and adolescents.

The 200/25 micrograms strength is used to treat asthma in adults and adolescents. The 200/25 micrograms strength is not for patients with COPD.

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).

How Relvar Ellipta works

Relvar Ellipta contains two active substances: fluticasone furoate and vilanterol. Two different strengths of Relvar Ellipta are available:

fluticasone furoate 100 micrograms/vilanterol 25 micrograms and fluticasone furoate 200 micrograms/vilanterol 25 micrograms.

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 small 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.

Before you use Relvar Ellipta

- When you must not use it
Do not use Relvar Ellipta

- if you are allergic to fluticasone furoate or vilanterol
- if you are allergic to lactose monohydrate
- if you are allergic to magnesium stearate
- if you think the above applies to you, don't use Relvar Ellipta until you have checked with your doctor.

- Before you start to use it

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 (100/25 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
- Check with your doctor before you use this medicine if you think any of these applies to you.

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.

- Taking other medicines

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 infection
- Ritonavir, to treat HIV infections
- Long-acting beta₂-adrenergic agonists, such as salmeterol

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

How to use Relvar Ellipta**- How much to use****Asthma**

The recommended dose to treat asthma is one inhalation (100 micrograms of fluticasone furoate and 25 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 (200 micrograms fluticasone furoate and 25 micrograms of vilanterol). This dose is also used once daily at the same time each day.

COPD

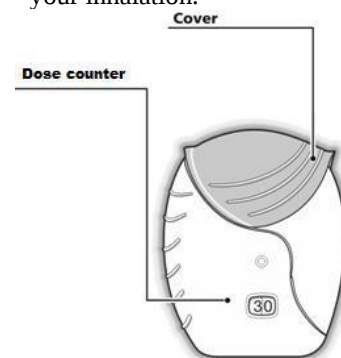
The recommended dose to treat COPD is one inhalation (100 micrograms of fluticasone furoate and 25 micrograms of vilanterol) once daily at the same time each day. The higher strength of Relvar Ellipta is not suitable for the treatment of COPD.

Step by step instructions

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, not even the first time you use it. 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.

Write the "Discard by" date on the inhaler label in the space provided. The "Discard by" date is 1 month from the date of first opening the tray. After this date do not use this inhaler any longer. You may discard the tray 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 will no longer be available. It is not possible to accidentally take extra medicine or a double dose in your inhalation.

**Cover**

Each time you open this, you prepare one dose of medicine

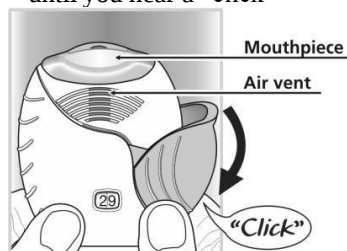
Dose counter

This shows how many doses of medicine are left in the inhaler. Before the inhaler has been used, it shows exactly 30 doses. It counts down by 1 each time you open the cover. When fewer than 10 doses are left, half of the dose counter shows red. After you have used the last dose, half of the dose counter shows red and the number 0 is displayed. Your inhaler is now empty. If you open the cover after this, the dose counter will change from half red to completely red.

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 (about 3-4 seconds).
- Remove the inhaler from your mouth.

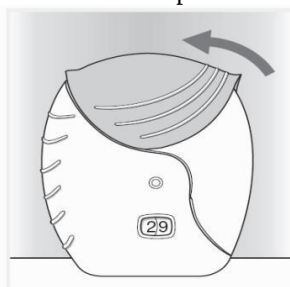
- Breathe out slowly and gently.

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.

- When to use it

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 long to use it

Take Relvar Ellipta for as long as your doctor recommends. Do not stop unless your doctor advises you to.

- If you forget to use it

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.

- If you use too much (overdose)

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.

While you are using it

- Things you must do

Contact your doctor if you experience blurred vision or other visual disturbances.

Contact your doctor if you experience increased thirst, frequent urination or unexplained tiredness (signs of high blood sugar)

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

Things you must not do

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.

- Things to be careful of
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 '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.

Side effects

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

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 spasm

Uncommon side effect

This may affect up to 1 in 100 people:

- Irregular heartbeat
- Blurred vision
- Increase in blood sugar (Hyperglycaemia)

Rare side effect

This may affect up to 1 in 1000 people:

- Allergic reaction, swelling of the skin, skin rash and red itchy bumps on the skin.
- Tremor
- Anxiety
- Palpitations (irregular heartbeat) and tachycardia (increased heart rate)
- Paradoxical bronchospasm (breathing or wheezing will get worse)

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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

Tell your doctor if you have any of the following while taking Relvar – they could be symptoms of a lung infection:

- Fever or chills;
- Increased mucus production or change in mucus colour;
- Increased cough or increased breathing difficulties.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF or Vaccines (AEFI))].

Storage and Disposal of Relvar Ellipta

- Storage

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 30°C. If stored in the refrigerator, allow the inhaler to return to room temperature for at least an hour before use. Store in the original package in order to protect from moisture and do not open the foil lid until ready to inhale.

Use within 1 month of first opening the tray.

Write the "Discard by" date on the inhaler label in the space provided, as soon as the inhaler is removed from the tray.

- Disposal

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.

Product Description

- What it looks like

Relvar is a white powder. The Ellipta device itself is a light grey inhaler with a pale blue 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.

- Ingredients

- Active ingredient(s)
Fluticasone furoate/vilanterol
(100/25 micrograms)
Or
Fluticasone furoate/vilanterol
(200/25 micrograms)

- Inactive ingredient(s)
Lactose monohydrate and
magnesium stearate

- MAL number

Relvar Ellipta 100/25
micrograms inhalation
powder, pre-dispensed
• MAL14115017ARZ

Relvar Ellipta 200/25
micrograms inhalation
powder, pre-dispensed
• MAL14115018ARZ

Manufacturer

GlaxoSmithKline LLC
1011 North Arendell Avenue
Zebulon
North Carolina 27597
USA

**Product Registration
Holder**

GlaxoSmithKline
Pharmaceutical Sdn. Bhd.
HZ.01, Horizon Penthouse,
1 Powerhouse,
1, Persiaran Bandar Utama,
Bandar Utama,
47800 Petaling Jaya
Selangor, Malaysia

Date of Revision
21/07/2023

Serial Number
NPRA (R1/5) 20072023/139