

Package leaflet: information for the patient

Relvar Ellipta 92 microgram /22 microgram inhalation powder, pre-dispensed
Relvar Ellipta 184 microgram /22 microgram inhalation powder, pre-dispensed
fluticasone furoate/vilanterol

Read the entire 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.
- Do you have any further questions? Please contact your doctor, pharmacist, or nurse.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not mentioned in this leaflet? Then contact your doctor, pharmacist, or nurse.

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1. What is Relvar Ellipta and what is it used for?

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

The 92/22 microgram strength is used for the regular treatment of chronic obstructive pulmonary disease (COPD) in adults and asthma in adults and adolescents aged 12 years and older.

The 184/22 microgram strength is used for the treatment of asthma in adults and adolescents aged 12 years and older. The 184/22 microgram strength is not approved for the treatment of 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 for the relief of a sudden attack of breathlessness or wheezing. If you have such an attack, you should use a fast-acting inhaler (such as salbutamol). If you do not have a fast-acting inhaler, contact your doctor.

Fluticasone furoate belongs to a group of medicines called corticosteroids, or steroids for short. Corticosteroids reduce inflammation. They reduce the swelling and irritation of the small airways in the lungs and thus gradually reduce breathing problems. Corticosteroids also help prevent asthma attacks and worsening of COPD.

Vilanterol belongs to a group of medicines called long-acting bronchodilators. It relaxes the muscles of the small airways in the lungs. This helps to open the airways, allowing air to move more easily in and out of the lungs. When used regularly, it helps to keep the small airways open.

When you regularly use these two active substances together, they help you keep your breathing problems better under control than when using either one separately. medications.

Asthma is a serious, long-term lung disease where the muscles around the smaller airways narrow (bronchoconstriction) and become swollen and irritated (inflammation). Symptoms occur occasionally and include shortness of breath, wheezing, chest tightness, and coughing. It has been shown that Relvar Ellipta reduces asthma flare-ups and symptoms. Chronic obstructive pulmonary disease (COPD) is a serious, long-term lung disease where the airways

become inflamed and thickened. Symptoms include shortness of breath, coughing, discomfort in the chest, and coughing up mucus. It has been shown that Relvar Ellipta reduces COPD symptom flare-ups. 2. When should you not use this medicine or be extra careful? When should you not use this medicine?

You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

If you think the above applies to you, do not use Relvar Ellipta until you have spoken with

- your doctor.
- When should you be extra careful with this medicine? Contact your doctor before using this medicine:

if you have liver disease, as you may be more likely to experience side effects. If you have a

Contact your doctor before using this medication:

- if you have liver disease, because you may be more likely to experience side effects. If you have a if you have moderate or severe liver disease, your doctor will limit your dose to the lower strength of Relvar Ellipta (once daily 92/22 micrograms)
- if you suffer from heart problems or high blood pressure
- if you have pulmonary tuberculosis (TB), or other long-lasting or untreated infections
- if you have ever been told that you have diabetes or high blood sugar levels
- if you have thyroid problems
- if you have low potassium levels in your blood
- if you suffer from blurred vision or other visual disturbances

Talk to your doctor before using this medicine if you think any of the above points apply to you.
While using Relvar Ellipta

Immediate breathing difficulties

If you experience tightness, coughing, wheezing, or shortness of breath immediately after using your

Relvar Ellipta inhaler: stop using this medicine and seek immediate medical help, as you may have a serious

condition called paradoxical bronchospasm. contact your doctor if you experience blurred vision or other vision problems

- contact your doctor if you become more thirsty, need to urinate frequently, or feel inexplicably tired
- (signs of high blood sugar levels) (signs of high blood sugar levels)

Lung infection

If you use this medicine for COPD, you may be at a higher risk of developing an infection of the lungs called pneumonia. See section 4 for information on symptoms to watch for when using this medicine. Tell your doctor as soon as possible if you develop any of these symptoms.

Children and adolescents under 18 years

Do not give this medicine to children under 12 years for the treatment of asthma, or to children and adolescents under 18 years for the treatment of COPD.

Are you taking any other medicines?

Are you taking any other medicines besides Relvar Ellipta, have you recently taken any, or is there a possibility that you will take other medicines in the near future? If so, tell your doctor or pharmacist. Also consult your doctor or pharmacist if you are unsure about what your medicine contains.

Some medicines can affect the action of this medicine or increase the risk of side effects. These include:

- medicines called beta-blockers, such as metoprolol, used for the treatment of high blood pressure or a heart problem
- ketoconazole, used for the treatment of fungal infections
- ritonavir or cobicistat, used for the treatment of HIV infections
- long-acting beta2-adrenergic agonists, such as salmeterol

Tell your doctor or pharmacist if you are taking any of these medicines. Your doctor may want to monitor you carefully if you are taking any of these medicines, as they can increase the side effects of Relvar Ellipta may worsen.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor before using this medicine. Do not use this medicine if you are pregnant, unless your doctor has told you that you can use it.

It is not known whether the substances in this medicine are excreted in breast milk. If you are breastfeeding, contact your doctor before using Relvar Ellipta. Do not use this medicine if you are breastfeeding, unless your doctor has told you that you can use it.

Driving and using machines

This medicine is unlikely to affect your ability to drive or use machines. Relvar Ellipta contains lactose

If your doctor has told you that you cannot tolerate certain sugars, contact your doctor before using this medicine. 3. How to use this medicine?

Always use this medicine exactly as your doctor has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist. Asthma

The recommended dosage for the treatment of asthma is one inhalation (92 micrograms fluticasone furoate and 22 micrograms vilanterol) once daily, at the same time each day. 22 microgram vilanterol) once daily, every day at the same time.

If you have severe asthma, your doctor may decide that you need to take one inhalation from the inhaler with the higher strength (184 micrograms fluticasone furoate and 22 micrograms vilanterol). This dose should also be taken once daily and at the same time every day.

COPD

The recommended dosage for the treatment of COPD is one inhalation (92 micrograms fluticasone furoate and 22 micrograms vilanterol) once daily, at the same time every day.

The higher strength of Relvar Ellipta (184 micrograms fluticasone furoate and 22 micrograms vilanterol) is not suitable for the treatment of COPD.

Relvar Ellipta is for oral inhalation.

Use Relvar Ellipta at the same time every day because it works for 24 hours.

It is very important that you use this medicine every day, as your doctor has told you. This will help keep you symptom-free day and night.

Relvar Ellipta should not be used for the relief of a sudden attack of shortness of breath or wheezing. If you have such an attack, you should use a fast-acting inhaler (such as salbutamol).

Contact your doctor if you become short of breath more often than usual or have wheezing more often, or if you use your fast-acting inhaler more than usual.

How to use Relvar Ellipta?

See the 'Step-by-step instructions for use' after section 6 of this leaflet for full information. Relvar Ellipta is for oral inhalation. You do not need to prepare the Relvar Ellipta inhaler in a special way prepare, even when you use the inhaler for the first time.

If your symptoms do not improve

If your symptoms (shortness of breath, wheezing, coughing) do not improve or even worsen, or if you need to use the fast-acting inhaler more frequently: contact your doctor as soon as possible.

Have you used too much of this medicine?

If you accidentally use more Relvar Ellipta than your doctor has prescribed, contact your doctor or pharmacist. If possible, show him or her the inhaler, the packaging, or this leaflet.

You may notice that your heart beats faster than normal, that you feel shaky, or that you get a headache. It is especially important to ask your doctor or pharmacist for advice if you have used more than prescribed for a longer period. Higher doses of Relvar Ellipta can reduce the amount of steroid hormones naturally produced by your body.

Have you forgotten to use this medicine?

Do not inhale a double dose to make up for a forgotten dose. Just take your next dose at the usual time.

If your breathing starts to wheeze, if you become short of breath, or have other symptoms of an asthma attack, use your fast-acting inhaler (e.g., salbutamol) and then consult a doctor.

Do not stop using Relvar Ellipta without advice

Use this medicine as long as your doctor recommends it. It is only effective as long as you use it. Do not stop using this medicine unless your doctor advises it, even if you feel better.

Do you have any other questions about the use of this medicine? Then contact 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 are rare (occur in less than 1 in 1,000

users). If you experience any of the following symptoms after using Relvar Ellipta, stop using this medicine and tell your doctor immediately. rash (hives) or redness

- swelling, sometimes of the face or mouth (angioedema)
- severe wheezing, coughing, or difficulty breathing
- suddenly feeling weak or light-headed (this may lead to fainting or loss of consciousness).
- Immediate breathing difficulties

Immediate breathing difficulties after using Relvar Ellipta are rare.

If your breathing worsens or if you experience more wheezing immediately after using

this medicine, stop using it and seek medical help immediately. Pneumonia (lung infection) (common side effect, occurs in less than 1 in 10 users)

Tell your doctor if you experience any of the following symptoms while using Relvar

Tell your doctor if you experience any of the following symptoms while using Relvar Ellipta – these may be symptoms of a lung infection:

- fever or chills
- increased production of mucus, change in the color of the mucus
- more frequent coughing or increased breathing difficulties.

Other side effects:

Very common side effects

These occur in more than 1 in 10 users:

- headache
- common cold.

Common side effects

These occur in less than 1 in 10 users:

- painful, raised spots in the mouth or throat caused by a fungal infection (candidiasis). Rinsing your mouth with water immediately after using Relvar Ellipta can help stop the development of this side effect.
- inflammation of the lungs (bronchitis)

- infection of nasal cavities or throat
- flu (influenza)
- pain and irritation at the back of the mouth and throat
- inflammation of the sinuses
- itchy nose, runny nose or blocked nose
- coughing
- voice disorders
- weakening of the bones, leading to fractures
- stomach pain
- back pain
- high temperature (fever)
- joint pain
- muscle spasms.

Sometimes occurring side effects

These occur in less than 1 in 100 users:

- irregular heartbeat
- blurred vision
- increased blood sugar (hyperglycemia).

Rarely occurring side effects

These occur in less than 1 in 1,000 users:

- faster heartbeat (tachycardia)
- awareness of heartbeat (palpitations)
- trembling/shaking
- anxiety.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system as mentioned in Appendix V. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How to store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You can find it on the box, the tray, and the inhaler after EXP. It includes a month and a year. The last day of that month is the expiry date.

Store the inhaler in the sealed tray to protect it from moisture and only remove it just before first use. Once the tray is opened, the inhaler can be used for a maximum of 6 weeks, counted from the day the tray was opened. Write the date the inhaler should be discarded on the inhaler's label

in the designated space. The date must be noted immediately once the inhaler is removed from the tray.

Store below 25°C.

If the inhaler is stored in the refrigerator, allow it to return to room temperature for at least one hour before use. Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist

what to do with medicines you no longer use. They will then be disposed of responsibly. what you should do with medicines you no longer use. They are then disposed of in a responsible manner destroyed and do not enter the environment.

6. Contents of the package and other information

What substances are in this medicine?

- The active substances in this medicine are fluticasone furoate and vilanterol.
- For the 92/22 mcg dose: each inhalation delivers a dose (the dose that comes out of the mouthpiece) of 92 micrograms of fluticasone furoate and 22 micrograms of vilanterol (as trifenate).
- For the 184/22 mcg dose: each inhalation delivers a dose (the dose that comes out of the mouthpiece) of 184 micrograms of fluticasone furoate and 22 micrograms of vilanterol (as trifenate).
- The other substances in this medicine are lactose monohydrate (see section 2 under 'Relvar Ellipta contains lactose') and magnesium stearate.

What does Relvar Ellipta look like and what does the package contain?

Relvar Ellipta is an inhalation powder, pre-dispensed.

The Ellipta inhaler consists of a light grey inhaler with a yellow mouthpiece cover and a dose counter. It is packaged in a laminate foil tray with a peelable foil closure. The tray contains a desiccant sachet to reduce moisture in the package. Discard the desiccant when you have opened the tray closure – the desiccant must not be eaten or inhaled. The inhaler does not need to be stored in the laminate foil tray once it is opened.

Relvar Ellipta is available in packages of 1 inhaler with 14 or 30 doses (supply for 14 or 30 days) and in multipacks with 90 (3 inhalers of 30) doses (supply for 90 days). Not all mentioned pack sizes are marketed.

Marketing authorization holder

GlaxoSmithKline Trading Services Limited
12 Riverwalk
Citywest Business Campus
Dublin 24

Ireland
D24 YK11

Manufacturer

Glaxo Wellcome Production
Zone Industrielle No.2
23 Rue Lavoisier
27000 Evreux
France

This leaflet was last approved in <{MM/YYYY}>.

Other sources of information

More information about this medicine is available on the website of the European Medicines Agency: <http://www.ema.europa.eu>.

Step-by-step instructions for use

What is the Ellipta inhaler?

The first time you use Relvar Ellipta, you do not need to check if it is working correctly and you also do not need to prepare it in a special way for use. You only need to follow these step-by-step instructions.

The box of your Relvar Ellipta inhaler contains

Cover foil of the tray

Box
Inhaler
This leaflet
Desiccant
Tray

The inhaler is packed in a tray. Do not open the tray until you are ready to inhale a dose of your medication. When you are ready to use your inhaler, pull the cover foil from the tray to open it. The tray contains a desiccant sachet to reduce moisture. Discard this desiccant sachet – it must not be opened, eaten, or inhaled.

Desiccant

When you take the inhaler out of the tray, it is in the 'closed' position. Do not open the inhaler until you are ready to inhale a dose of the medication. Once the tray is opened, write the 'Discard by' date on the label of the inhaler in the designated space. The 'Discard by' date is 6 weeks after the date the tray was opened. From this date, you must not use the inhaler anymore. The tray can be discarded after opening.

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

The instructions for use of the Ellipta inhaler below apply to both the Ellipta inhaler with 30 doses (supply for 30 days) and the Ellipta inhaler with 14 doses (supply for 14 days).

1. Read this before you start

If you open or close the cover without inhaling the medicine, the dose will be lost. The lost dose is safely held in the inhaler but is no longer available. It is not possible to accidentally take extra medicine or a double dose during an inhalation.

2. Preparing a dose

Wait to open the cover until you are ready to inhale your dose. Do not shake the inhaler.

- Slide the cover down until you hear a 'click'.

Your medicine can now be inhaled.
The dose counter counts down by 1 to confirm this.

- If the dose counter does not count down when you hear the 'click', the inhaler will not release any medicine. Return the inhaler to your pharmacist for advice.

3. Inhaling the medicine

- Breathe out as deeply as possible while holding the inhaler away from your mouth. Do not exhale into the inhaler.
- Place the mouthpiece between your lips and close your lips firmly around it. Do not block the air opening with your fingers.
- Inhale once, long, evenly, and deeply. Hold your 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 taste or feel the medicine, even if you use the inhaler correctly. used.

4. Close the inhaler and rinse your mouth

- Slide the protective cap up as far as possible to cover the mouthpiece.
- Rinse your mouth with water after using the inhaler and do not swallow it.

This makes it less likely that you will get a sore mouth or throat as a side effect.

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