

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed according to a physician's prescription only

Relvar Ellipta 92/22 mcg, powder for inhalation

Each dose released from the Ellipta inhaler contains:

92 mcg Fluticasone furoate/22 mcg Vilanterol (as trifenate).

Relvar Ellipta 184/22 mcg, powder for inhalation

Each dose released from the Ellipta inhaler contains:

184 mcg Fluticasone furoate/22 mcg Vilanterol (as trifenate).

For the list of the inactive and allergenic ingredients in the medicine, see section 2 - "Important information about some of the ingredients in the medicine" and section 6 - "Additional information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED 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 mcg 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 mcg strength is used to treat **asthma** in adults and adolescents aged 12 years and older.

The 184/22 mcg strength is not approved for the treatment of chronic obstructive pulmonary disease (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). If you do not have a quick-acting inhaler, contact your physician.

Therapeutic group:

Vilanterol is a beta-2 receptor agonist. Fluticasone furoate is a corticosteroid. Fluticasone furoate belongs to a group of medicines called corticosteroids, sometimes also 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 of them 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. Relvar Ellipta has been shown to reduce flare-ups and symptoms of asthma.

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. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to fluticasone furoate, vilanterol or to any of the additional ingredients contained in this medicine (listed in section 6).
- you think the above applies to you, **do not use Relvar Ellipta** until you have checked with your physician.

Special warnings regarding use of the medicine

Before the treatment with Relvar Ellipta, tell the physician if:

- you have **liver disease**, as you may be more likely to experience side effects.
If you have moderate or severe liver disease, your physician will limit your dose to the lower strength of Relvar Ellipta (92/22 micrograms, once daily).
 - you have **heart problems** or **high blood pressure**.
 - you have tuberculosis (TB) of the lung, or any long-standing or untreated infections.
 - you have ever been told that you have diabetes or high blood sugar level.
 - you have **thyroid gland problems**.
 - you have **low potassium levels** in your blood.
 - you experience blurred vision or other visual disturbances.
- **Check with your physician** before you use this medicine if you think any of these applies to you.

While you are using Relvar Ellipta

Breathing difficulties immediately after use of Relvar Ellipta

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

- **Stop using this medicine and seek medical help immediately**, as you may have a serious condition called paradoxical bronchospasm.
- Contact your physician if you experience blurred vision or other visual disturbances.

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

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 for information on symptoms to look out for while you are using this medicine. Tell your physician as soon as possible if you develop any of these symptoms.

Children and adolescents

Do not give this medicine to 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.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the physician or pharmacist. If you are not sure what your medicine contains, talk to your physician or pharmacist.

Some medicines may affect how this medicine works, or make it more likely that you will have side effects. Particularly if you are taking:

- Medicines called beta-blockers, such as metoprolol, used to treat **high blood pressure** or **heart problems**.
 - Ketoconazole, to treat **fungus infections**.
 - Ritonavir or cobicistat, to treat **HIV infections**.
 - Long-acting beta-2 adrenergic agonists, such as salmeterol.
- **Tell your physician or pharmacist** if you are taking any of these medicines.

Your physician may wish to monitor your condition carefully if you are taking one or more of these medicines, as they may increase the side effects of Relvar 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 physician for advice before using this

medicine. Do not use this medicine if you are pregnant unless your physician has told 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 physician** before using Relvar Ellipta. Do not use this medicine if you are breast-feeding unless your physician has told you that you can.

Driving and using machines

It is unlikely that this medicine will affect your ability to drive or use machines.

Important information about some of the ingredients in the medicine

Relvar Ellipta contains lactose

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

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the physician's instructions. Check with the physician or pharmacist if you are uncertain about the preparation dosage and treatment regimen.

The dosage and treatment regimen will be determined by the physician only.

Asthma

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

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

COPD

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

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

Relvar Ellipta is for oral inhalation.

Do not exceed the recommended dose.

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 physician. 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 a quick-acting inhaler more than usual, refer to your physician.

How to use Relvar Ellipta

See 'Step-by-step instructions' 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 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 a quick-acting inhaler more often:

→ **Contact your physician as soon as possible.**

If you accidentally have taken a higher dosage

If you have accidentally taken a higher dosage of Relvar Ellipta than your physician has instructed you to, refer to your physician or pharmacist. 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 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 physician 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 took an overdose or if a child has accidentally taken the medicine, refer immediately to a physician or to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine

If you forgot to take this medicine at the required time, do not inhale a double dose to make up for the forgotten dose. Take your next dose at the usual time. If you become breathless or start wheezing, 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

Adhere to the treatment regimen as recommended by the physician. The medicine will only be effective as long as you are using it. Do not stop treatment, even if you feel better, unless your physician has instructed you to do so.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Relvar Ellipta may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

Allergic Reactions

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

If you have any of the following symptoms after taking Relvar Ellipta, **stop taking this medicine and tell your physician immediately:**

- Skin rash (*hives - itchy lumps*) or redness
- Swelling, sometimes of the face or mouth (*angioedema*)
- You may become very wheezy, cough or have breathing difficulties
- Suddenly feeling weak or light-headed (which may lead to collapse or loss of consciousness)

Breathing difficulties immediately after use of Relvar Ellipta

Breathing difficulties immediately after use of Relvar Ellipta are rare.

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

Pneumonia (infection of the lungs) (common side effect, may affect up to 1 in 10 people)

Tell your physician if you have any of the following while using 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

Additional side effects:

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 effects

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

- Irregular heartbeat
- Blurred vision
- Increased blood sugar level (*hyperglycemia*)

Rare side effects

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

- Heart beating faster (*tachycardia*)
- Awareness of heart beats (*palpitations*)
- Tremor
- Anxiety

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the physician.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il/>

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- Do not use the medicine after the expiry date (exp. date) that appears on the carton box, tray and inhaler. The expiry date refers to the last day of that month.
- Store the inhaler in the original package in order to protect from moisture and only remove take it out immediately before first use. Do not open the tray until the start of use. The inhaler can be used for up to 6 weeks, starting from the date of opening the tray, but not later than the expiry date. When taking the inhaler out of the tray, the "Discard by" date should be written on the back label of the inhaler and carton box, in the designated spot.
- Do not store above 25°C.
- If you store the inhaler in the refrigerator, **allow the inhaler to return to room temperature for at least an hour** before use.
- Do not discard medicines in the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

- In addition to the active ingredients, the medicine also contains:

Lactose monohydrate, magnesium stearate.

Also see section 2 - "Important information about some of the ingredients of the medicine".

- What the medicine looks like and the contents of the package:

Relvar Ellipta is an inhalation powder. The Ellipta inhaler itself is a light grey plastic inhaler with a pale blue mouthpiece cover and a dose counter. It is packaged in an aluminium tray with a peelable aluminium cover. The tray contains a *desiccant sachet* to reduce moisture in the packaging. Once you have opened the cover of the tray, throw the desiccant sachet away - do not eat or inhale it. The inhaler does not need to be stored in the aluminium tray once it has been opened.

Relvar Ellipta packages contain 1 inhaler containing 14 doses (that are sufficient for 14 days of treatment) or 30 doses (sufficient for 30 days of treatment).

Not all package sizes may be marketed.

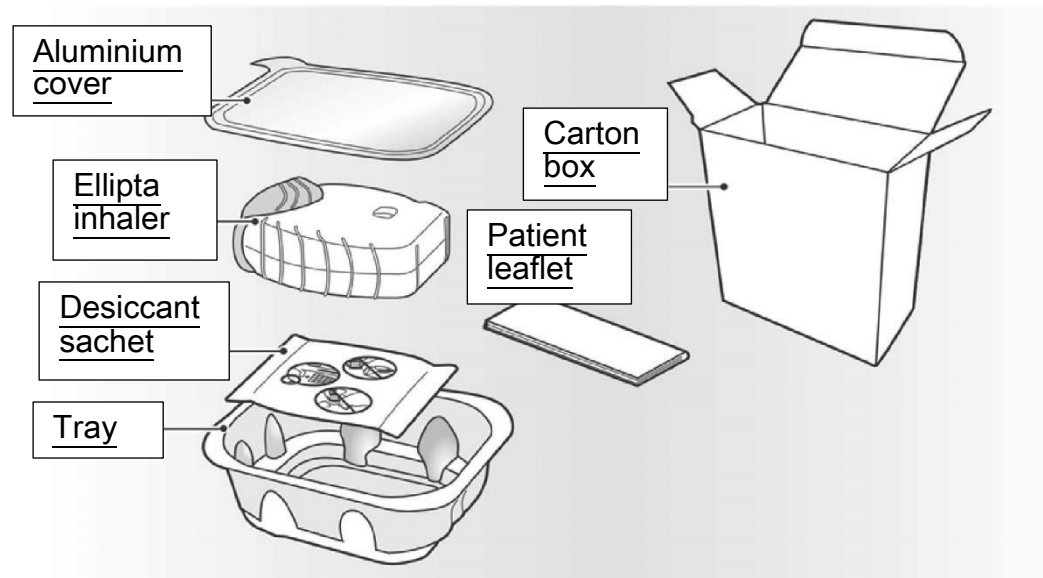
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: Glaxo Operations UK Ltd. (Glaxo Wellcome Operations), Ware, UK.
- Registration numbers of the medicines in the National Drug Registry of the Ministry of Health:
Relvar Ellipta 92/22 mcg: 151-45-33982
Relvar Ellipta 184/22 mcg: 151-46-33981

Step-by-step instructions for use

What is the Ellipta inhaler?

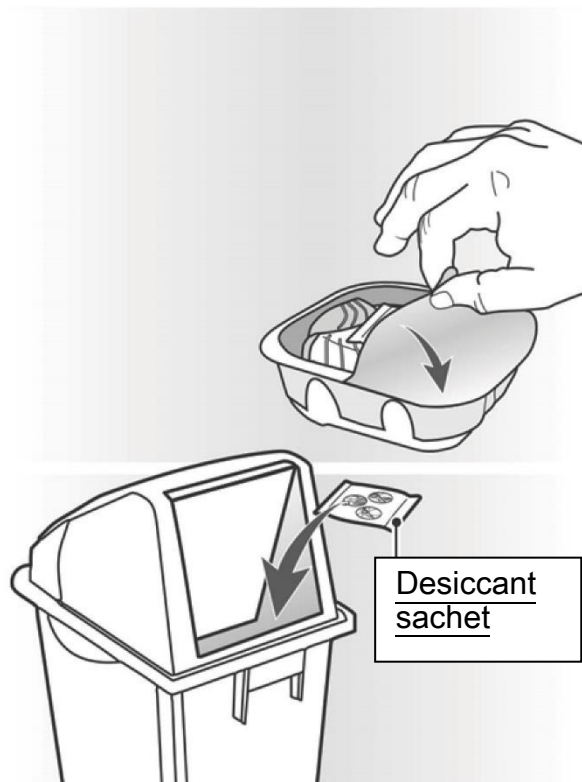
The first time you use Relvar Ellipta you do not need to check that it is working properly, and you do not need to prepare it for use in any special way. Just follow these step-by-step instructions.

The carton box of your Ellipta inhaler contains:



The inhaler is packaged in a tray. **Do not open the tray until you are ready to start using your medicine.** When you are ready to use the inhaler, peel back the aluminium cover to open the tray.

The tray contains a **desiccant sachet**, to reduce moisture. Throw this sachet away – **do not** open, inhale or eat 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 opening the tray, write the "Discard by" date on the inhaler back label and the carton box, in the designated spot. The "Discard by" date is 6 weeks from the date you first open the tray, but no later than the expiry date. **After this date, the inhaler should no longer be used.** The tray can be discarded after first opening.

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

The instructions for use of the inhaler shown below can be used for the 30-dose inhaler (30 day supply) or the 14-dose inhaler (14 day supply).

1. Read this information 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 an extra dose or a double dose in one inhalation.

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.

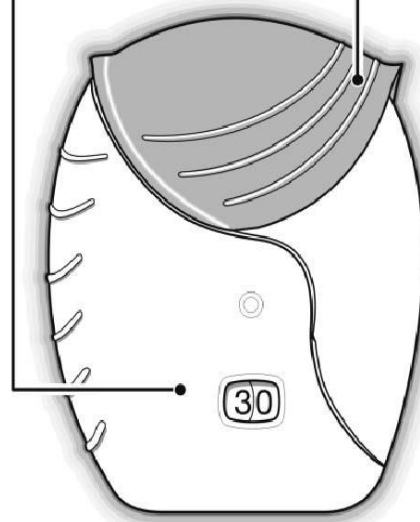
After you have used the last dose, half of the dose counter shows red and the number 0 is displayed.

Your inhaler is now empty.

If you open the cover after this, the dose counter will change to completely red.

Cover

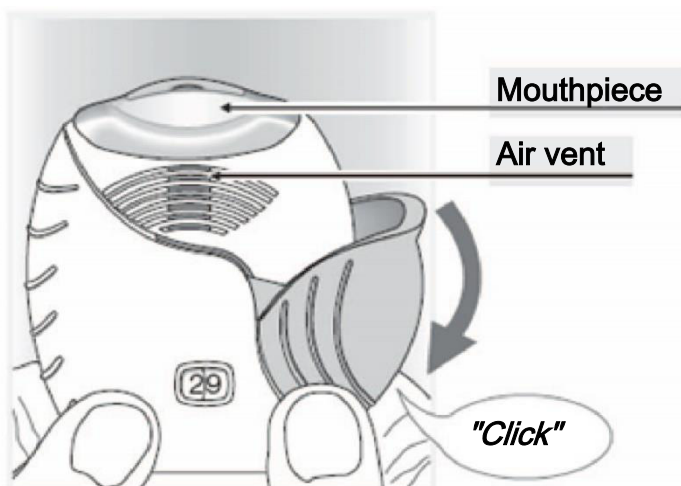
Each time you open this, you prepare one dose of medicine.



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. Return to your pharmacist for advice.

3. Inhale your medicine

- While holding the inhaler away from your mouth, breathe out as much as you can.

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.



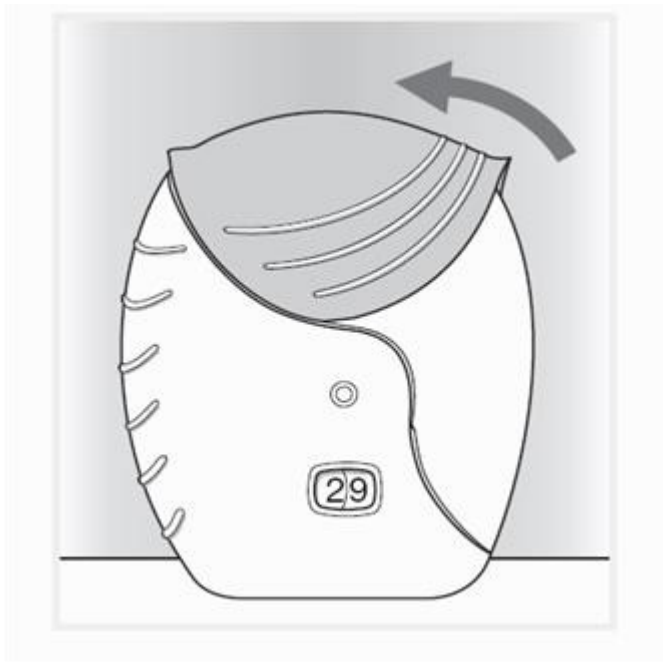
Your lips fit over the contoured shape of the mouthpiece for inhaling.

Do not block the air vent with your fingers.

- Take one long, deep and steady 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.
- 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.

Revised in September 2023 according to MoH guidelines.

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