PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

RELVAR Ellipta 92/22 µg inhalation powder, pre-dispensed

RELVAR Ellipta 184/22 µg inhalation powder, pre-dispensed

Fluticasone furoate/vilanterol

Contains sugar (lactose monohydrate 25 mg/dose).

Read all of this leaflet carefully before you start using RELVAR.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- RELVAR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What RELVAR is and what it is used for
2. What you need to know before you use RELVAR
3. How to use RELVAR
4. Possible side effects
5. How to store RELVAR
6. Contents of the pack and other information.

1. What RELVAR is and what it is used for:

RELVAR is used to treat **asthma** and **chronic obstructive pulmonary disease (COPD).**

RELVAR 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* or cortisone. Corticosteroids reduce inflammation.

Vilanterol belongs to a group of medicines called *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.

2. What you need to know before you use RELVAR:

Do not use RELVAR:

- if you are allergic (*hypersensitive*) to lactose or milk protein
- if you are allergic (*hypersensitive*) to fluticasone furoate, vilanterol or any other ingredients of RELVAR (listed in section 6).

If you think either of these applies to you, **don't use** RELVAR until you have checked with your doctor.

Warnings and precautions:

Talk to your doctor before you use RELVAR:

- 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 µg once daily)
- if you have heart problems or high blood pressure

- if you have an overactive thyroid
- if you have ever been told you have diabetes or high blood sugar
- if you have low blood potassium levels, as treatment with RELVAR can make this condition worse
- if you are taking medicines called beta-blocking medicines (such as atenolol or propranolol)
- if you have a serious lung infection e.g. tuberculosis (TB) or pneumonia.

Check with your doctor before you use RELVAR if you think any of these apply to you**.**

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

While you are using RELVAR contact your doctor if:

- you experience blurred vision or other visual disturbances
- you experience increased thirst, frequent urination, or unexplained tiredness (signs of high blood sugar).

Children and adolescents:

Do not give RELVAR 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.

Other medicines and RELVAR:

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicine.)

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

- ketoconazole, to treat fungal infections

- ritonavir, to treat HIV infections
- beta-blocking medicines (such as atenolol or propranolol, used to treat heart disease).

Tell your doctor or pharmacist if you are taking this medicine.

Pregnancy and breastfeeding and fertility:

If you are pregnant or breastfeeding think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other healthcare provider for advice before you start using RELVAR.

Pregnancy: You should not use RELVAR when pregnant.

Breastfeeding: You should not use RELVAR when breastfeeding.

Driving and using machines:

It is unlikely that RELVAR will affect your ability to drive or use machines. However, do not drive or use machinery if you do not feel well.

RELVAR contains lactose monohydrate:

If you are known with the rare hereditary conditions of lactose/fructose or galactose intolerance, you should not use RELVAR.

3. How to use RELVAR:

Always use RELVAR exactly as your doctor has told you to. Check with your doctor, nurse or pharmacist if you're not sure.

The usual dose of RELVAR for asthma and COPD is one inhalation of RELVAR 100/25 µg 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 of RELVAR inhaler. This dose is also used once daily at the same time each day.

It is very important that you use RELVAR every day, as instructed by your doctor.

RELVAR 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 the inhaler:

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

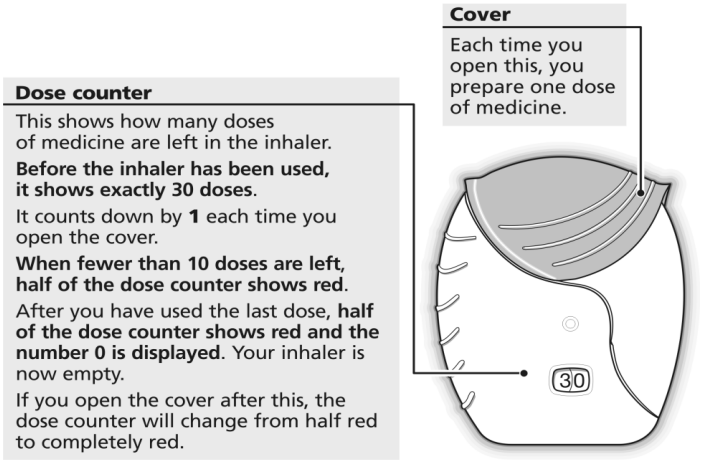
The inhaler is packaged in a tray. Do not open the tray until you are ready to inhale a dose of your medicine. When you are ready to use your inhaler, peel back the lid to open the tray. The tray contains a *desiccant* sachet, to reduce moisture. Throw this desiccant sachet away - **don't** open, eat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

When you take the inhaler out of its box, 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 in the space provided. The "Discard by" date is 6 weeks from the date you first open the tray. After this date, the inhaler should no longer be used.

Read this before you start:

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

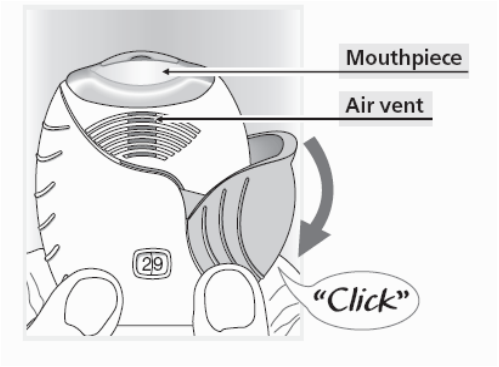
The lost dose will be securely held inside the inhaler, but it will no longer be available. It is not possible to accidentally take extra medicine or a double dose in one inhalation.



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.
- Do not shake the inhaler at any time.

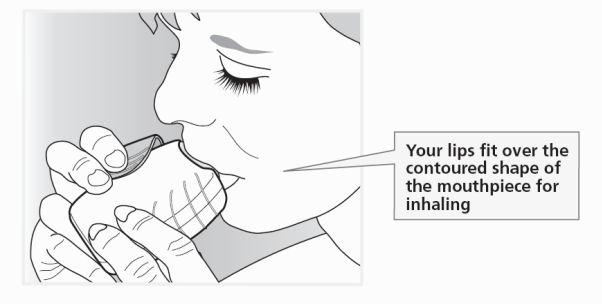
Inhale your medication:

- 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.



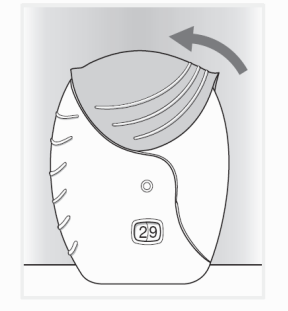
- Take one long, steady, deep breath in. Hold this breath for as long as possible (at least 3-4 seconds).
- Remove the inhaler from your mouth.
- Breathe out slowly and gently.

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

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

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 if possible.

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

If you use more RELVAR than you should:

If you accidentally use a larger dose of RELVAR 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 larger doses 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 may reduce the amount of steroid hormones produced naturally by your body.

If you forget to use RELVAR:

Don't take an extra dose to make up for a missed 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.

Don’t stop RELVAR withour advice:

Use RELVAR for as long as your doctor recommends. It will only be effective as long as you are using it. Don’t stop unless your doctor advises you to, even if you feel better.

4. Possible side effects:

RELVAR can have side effects.

Not all side effects reported for RELVAR are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using RELVAR, please consult your doctor, pharmacist, or other healthcare provider for advice.

Allergic reactions:

If any of the following happens, stop using RELVAR and tell your doctor immediately of go to the casualty department at your nearest hospital:

- skin rash (hives) or redness

- swelling, sometimes of the face or mouth (angioedema)
- becoming more wheezy, coughing or having difficulty in breathing
- suddenly feeling weak or lightheaded (may lead to collapse or loss of consciousness).

These are all very serious side effects. If you have them, you may have had a serious reaction to RELVAR. You may need urgent medical attention or hospitalisation.

Immediate breathing difficulties:

If your breathing or wheezing gets worse shortly after you inhaled RELVAR, **stop using it immediately,** and **contact your doctor** as soon as possible.

Infection of the lungs:

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 sputum production, change in sputum colour
- increased cough or increased breathing difficulties.

Frequent side effects include:

- headache
- common cold
- sore, raised patches in the mouth or throat caused by a fungal infection (*candidiasis*). Rinsing your mouth out with water immediately after using RELVAR may help prevent this side effect developing
- infection of the lungs *(pneumonia)*

- inflammation of the airways 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, including hoarseness due to sores in the throat
- abdominal pain (*stomach pain*)
- joint pain
- back pain
- weakening of the bones, leading to fractures.
- high temperature (*fever*)
- muscle spasms.

Less frequent side effects include:

- heart palpitations
- heart beating faster (tachycardia)
- awareness of heartbeat (palpitations)
- increase in blood sugar (hyperglycaemia)
- anxiety
- tremor.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of RELVAR ELLIPTA.

5. How to store RELVAR

Store at or below 25 °C.

Following removal from the tray, the product may be stored for a maximum period of 6 weeks when stored at or below 25 °C. 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 stored in the refrigerator, allow the inhaler to return to room temperature for at least an hour before use.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What RELVAR contains:

RELVAR contains two active ingredients: fluticasone furoate and vilanterol.

Each pre-dispensed dose contains either 100/25 µg or 200/25 µg of fluticasone furoate/vilanterol (as trifenatate).

Each single inhalation of fluticasone furoate/vilanterol provides a delivered dose of 92/22 µg of fluticasone furoate/vilanterol or 184/22 µg of fluticasone furoate/vilanterol.

The inactive ingredients are lactose monohydrate and magnesium stearate.

What RELVAR looks like and contents of the pack:

The plastic Ellipta inhaler consists of a light grey body, a pale blue mouthpiece cover and a dose counter, packed into a foil laminate tray containing a desiccant packet. The tray is sealed with a peelable foil lid.

The inhaler contains two strips of 30 regularly distributed blisters, each blister containing a single dose of white powder.

Each Ellipta inhaler is packed into a carton.

The Ellipta inhaler is available in a pack size that delivers 30 inhalations.

The blister strip consists of a formed silver coloured base foil laminate, sealed with a peelable lid foil laminate. Each blister strip contains 31 (30 dose) regularly distributed blisters. Each strip contains one empty blister which allows for correct location of the strip and test actuation of the inhaler.

Holder of Certificate of Registration:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

This leaflet was last revised:

22 May 2024

Registration numbers:

RELVAR Ellipta 92/22 µg: 48/21.5.1/0249

RELVAR Ellipta 184/22 µg: 48/21.5.1/0250

Date of registration:

16 February 2017

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