



Rolenium®
Fluticasone propionate
+Salmeterol

Rolenium Inhalation Powder, Pre-Dispensed
Fluticasone propionate/Salmeterol
(100+50), (250+50) and (500+50)
microgram/dose

Read all of this 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.
- If you have any further questions, ask your doctor or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

- What is in this leaflet:**
1. What **Rolenium** is and what it is used for
 2. What you need to know before you use **Rolenium**
 3. How to take **Rolenium**
 4. Possible side effects
 5. How to store **Rolenium**
 6. Further information

1. What Rolenium is and what it is used for

Rolenium contains two medicines, salmeterol and fluticasone propionate:

- Salmeterol is a long-acting bronchodilator. Bronchodilators help the airways in the lungs to stay open. This makes it easier for air to get in and out. The effects last for at least 12 hours.
- Fluticasone propionate is a corticosteroid which reduces swelling and irritation in the lungs.

The doctor has prescribed this medicine to help prevent breathing problems such as:

- Asthma.
- Chronic Obstructive Pulmonary Disease (COPD).

Rolenium at a dose of 500/50 micrograms, reduces the number of flare ups of COPD. You must use **Rolenium** every day as directed by your doctor. This will make sure that it works properly in controlling your asthma or COPD. **Rolenium helps to stop breathlessness and wheeziness coming on. However, Rolenium should not be used to relieve a sudden attack of breathlessness or wheezing. If this happens you need to use a fast-acting “reliever” (‘rescue’) inhaler, such as salbutamol. You should always have your fast-acting ‘rescue’ inhaler with you.**

2. Before you use Rolenium

Do not take Rolenium if

- You are allergic to salmeterol and/or fluticasone propionate or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using **Rolenium** if you have:

- Heart disease, including an irregular or fast heartbeat.
- Overactive thyroid gland.
- High blood pressure.
- Diabetes mellitus (**Rolenium** may increase your blood sugar).
- Low potassium in your blood.
- Tuberculosis (TB) now or in the past, or other lung infections.

Other medicines and Rolenium

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines for asthma or any medicines obtained without prescription. Tell your doctor if you are taking the following medicines, before starting to use **Rolenium**:

- B- blockers (such as atenolol, propranolol, sotalol). B- blockers are mostly used for high blood pressure or other heart conditions.
- Medicines to treat infections (such as ritonavir, cobicistat, ketoconazole, itraconazole and erythromycin). Some medicines may increase the effects of **Rolenium** and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat). This can increase your risk of experiencing side effects with **Rolenium**, including irregular heartbeats, or may make side effects worse.
- Corticosteroids (by mouth or by injection). If you have had these medicines recently, this might increase the risk of this medicine affecting your adrenal gland.
- Diuretics, also known as ‘water tablets’ used to treat high blood pressure.
- Other bronchodilators (such as salbutamol).
- Xanthine medicines. These are often used to treat asthma.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Rolenium is not likely to affect your ability to drive or use machines

Rolenium contains lactose

The amount of lactose in this medicine does not normally cause problems in people who are lactose intolerant. The excipient lactose contains small amounts of milk proteins, which may cause allergic reactions.

3. How to use Rolenium

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

- Use your **Rolenium** every day until your doctor advises you to stop. Do not take more than the recommended dose. Check with your doctor or pharmacist if you are not sure.
- Do not stop taking **Rolenium** or reduce the dose of **Rolenium** without talking to your doctor first.
- **Rolenium** should be inhaled through the mouth into the lungs.
- After use rinse your mouth with water and spit it out.

For adults and adolescents aged 12 years and over with asthma.

Rolenium 100/50 microgram/ dose: One inhalation twice a day.
Rolenium 250/50 microgram/ dose: One inhalation twice a day
Rolenium 500/50 microgram/dose: One inhalation twice a day.

For children aged 4 to 12 years with asthma

Rolenium 100/50 microgram/ dose: One inhalation twice a day.
Rolenium is not recommended for use in children below 4 years of age.

For adults with Chronic Obstructive Pulmonary Disease (COPD)

- **Rolenium** 500/50 microgram/dose: One inhalation twice a day.

Your symptoms may become well controlled using **Rolenium** twice a day. If so, your doctor may decide to reduce your dose to once a day. The dose may change to:

- Once at night - if you have **night-time** symptoms.
- Once in the morning - if you have **daytime** symptoms.

It is very important to follow your doctor’s instructions on how many inhalations to take and how often to take your medicine. If you are using **Rolenium** for asthma, your doctor will want to regularly check your symptoms.

If your asthma or breathing gets worse tell your doctor straight away.

You may find that you feel more wheezy, your chest feels tight more often or you may need to use more of your fast acting ‘reliever’ medicine. If any of these happen, you should continue to take **Rolenium** but do not increase the number of puffs you take. Your chest condition may be getting worse and you could become seriously ill. See your doctor as you may need additional treatment.

Instructions for use

Your doctor or pharmacist should show you how to use your inhaler (Elpenhaler). They should check how you use it from time to time. Not using the **Rolenium** properly or as prescribed may mean that it will not help your asthma or COPD as it should.

INSTRUCTIONS FOR USE AND HANDLING OF THE ELPENHALER

The following are instructions to the patient for the proper inhalation of the two medicines packed in the two blisters of the single dose strips (double-blister strips), which are stored in the Elpenhaler.

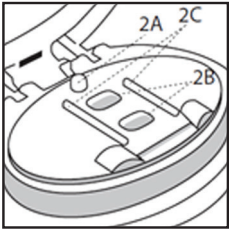
DESCRIPTION

The Elpenhaler is a device for inhaling at the same time two medicines which are in the form of powder. The two medicines form in one medicinal combination. Each medicine is packed separately from the other in one of the two blisters of the specially designed double-blister strip. The double-blister strip contains one (1) dose of the medicinal combination.



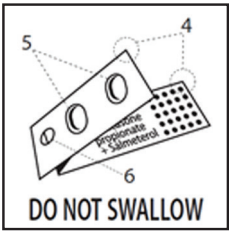
- The Elpenhaler is comprised of 3 parts:
- The mouthpiece and its cap **(1)**.
 - The surface **(2)** on which the double-blister strip is placed (drug supporting surface).
 - The storage case **(3)** which houses the double-blister strips.

The three parts are connected to each other and can be opened separately.



The drug supporting surface contains:

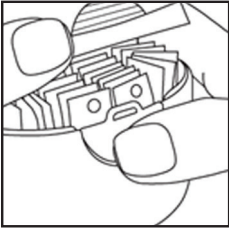
- An attachment point **(2A)** where the double-blister strip is attached.
- Two cavities **(2B)** which accommodate the two blisters of the strip.
- Two strip guides **(2C)** which firmly secure the double-blister strip in the correct position on the drug supporting surface.



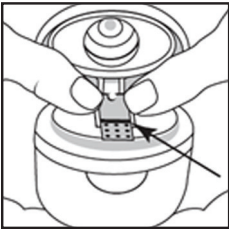
The double-blister strip contains:

- Two aluminium sheets **(4)**.
- Two blisters **(5)**, one containing salmeterol and the other fluticasone propionate.
- A hole **(6)**.

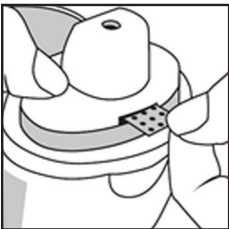
USE OF THE ELPENHALER
A. Preparing the device



Open the storage case by pressing as in the figure, take a strip and close the storage case again.



Uncover the mouthpiece completely by applying light pressure on the striped area. Unlock and push the mouthpiece backwards so as to reveal the drug supporting surface. Hold the double-blister strip with its shiny surface upwards, so as to see the blue line, as shown by the arrow in the figure. The labelled surface of the strip should face downwards. Place the hole of the strip on the attachment point of the drug supporting surface. By applying light pressure make sure the strip is securely attached on the attachment point. The two blisters of the strip will fit in the cavities of the supporting surface and the guides will secure the strip in the correct position.



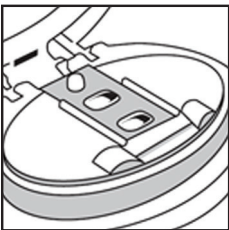
Close the mouthpiece and pull away horizontally the embossed protruding end of the strip to be detached. The dose is now ready to be inhaled.

B. Inhalation of the dose

Hold the device away from your mouth. Exhale completely. Be careful not to exhale on the mouthpiece of the device. Bring the Elpenhaler to your mouth and place your lips tightly around the mouthpiece.



Breathe in slowly and deeply from your mouth (and not from your nose) until your lungs are full. Hold in your breath approximately 5 seconds or as long as you comfortably can and at the same time remove the device from your mouth. Exhale and continue to breathe normally.



Open the mouthpiece. You will notice that you have inhaled all the powder and that the blisters of the strip are empty. Remove the empty strip and proceed to step C.

C. Cleaning the device

Following each use, wipe the mouthpiece and the drug supporting surface with a dry cloth or dry paper tissue. Do not use water to clean the device. Close the mouthpiece and its cap.

If you use more Rolenium than you should

It is important to use the inhaler as instructed. If you accidentally take a larger dose than recommended, talk to your doctor or pharmacist. You may notice your heart beating faster than usual and that you feel shaky. You may also have dizziness, a headache, muscle weakness and aching joints. If you have used larger doses for a long period of time, you should talk to your doctor or pharmacist for advice. This is because larger doses of **Rolenium** may reduce the amount of steroid hormones produced by the adrenal gland.

If you forget to use Rolenium

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

If you stop using Rolenium

It is very important that you take your **Rolenium** every day as directed. **Keep taking it until your doctor tells you to stop. Do not stop or suddenly reduce your dose of Rolenium.** This could make your breathing problem worse. In addition, if you suddenly stop taking **Rolenium** or reduce your dose of **Rolenium** this may (very rarely) cause you to have problems with your adrenal gland (adrenal insufficiency) which sometimes causes side effects.

These side effects may include any of the following:

- Stomach pain.
- Tiredness and loss of appetite, feeling sick.
- Sickness and diarrhoea.
- Weight loss.
- Headache or drowsiness.
- Low levels of potassium in your blood.
- Low blood pressure and seizures (fits).

When your body is under stress such as from fever, trauma (such as a car accident), infection, or surgery, adrenal insufficiency can get worse and you

may have any of the side effects listed above. If you get any side effects, talk to your doctor or pharmacist. To prevent these symptoms occurring, your doctor may prescribe extra corticosteroids in tablet form (such as prednisolone). If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. To reduce the chance of side effects, your doctor will prescribe the lowest dose of **Rolenium** to control your asthma or COPD. **Allergic reactions: you may notice your breathing suddenly gets worse immediately after using Rolenium.** You may be very wheezy and cough or be short of breath. You may also notice itching, a rash (hives) and swelling (usually of the face, lips, tongue or throat), or you may suddenly feel your heart beating very fast or you feel faint and light headed (which may lead to collapse or loss of consciousness). **If you get these effects or if they happen suddenly after using Rolenium, tell your doctor straight away.** Allergic reactions to **Rolenium** are uncommon (they may affect up to 1 in 100 people).

Pneumonia (infection of the lung) in COPD patients (Common side effect).

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

- Fever or chills.
- Increased mucus production, change in mucus color
- Increased cough or increased breathing difficulties.

Other side effects are listed below:

- Very common:** may affect more than 1 in 10 people
- Headache: this usually gets better as treatment continues.
- Increased number of colds has been reported in patients with COPD.

Common: may affect up to 1 in 10 people

- Thrush (sore, creamy-yellow, raised patches) in the mouth and throat. Also, sore tongue and hoarse voice and throat irritation. Rinsing your mouth out with water and spitting it out immediately and/or brushing your teeth after taking each dose of your medicine may help. Your doctor may prescribe an antifungal medication to treat the thrush.
- Aching, swollen joints and muscle pain.
- Muscle cramps.

The following side effects have also been reported in patients with Chronic Obstructive Pulmonary Disease (COPD):

- Bruising and fractures.
- Inflammation of sinuses (a feeling of tension or fullness in the nose, cheeks and behind the eyes, sometimes with a throbbing ache).
- A reduction in amount of potassium in the blood (you may get an uneven heartbeat, muscle weakness, cramp).

Uncommon: may affect up to 1 in 100 people

- Increases in the amount of sugar (glucose) in your blood (hyperglycaemia). If you have diabetes, more frequent blood sugar monitoring and possibly adjustment of your usual diabetic treatment may be required.
- Cataract (cloudy lens in the eye).
- Very fast heartbeat (tachycardia).
- Feeling shaky (tremor) and fast or uneven heartbeat (palpitations) – these are usually harmless and get less as treatment continues.
- Feeling worried (this effect mainly occurs in children).
- Disturbed sleep.
- Chest pain.
- Allergic skin rash.

Rare: may affect up to 1 in 1,000 people

- **Breathing difficulties or wheezing that get worse straight after taking Rolenium.** If this happens stop using **Rolenium**. Use your fast-acting ‘reliever’ inhaler to help your breathing and tell your doctor straight away.
 - **Rolenium** may affect the normal production of steroid hormones in the body, particularly if you have taken high doses for long periods of time. The effects include:
 - Slowing of growth in children and adolescents.
 - Thinning of the bones.
 - Glaucoma.
 - Weight gain.
 - Rounded (moon shaped) face (Cushing’s Syndrome).
- Your doctor will check you regularly for any of these side effects and make sure you are taking the lowest dose of **Rolenium** to control your asthma. Behavioural changes, such as being unusually active and irritable (these effects mainly occur in children).
- Uneven heartbeat or heart gives an extra beat (arrhythmias). Tell your doctor, but do not stop taking **Rolenium** unless the doctor tells you to stop.
 - A fungal infection in the oesophagus (gullet), which might cause difficulties in swallowing.

Not known: frequency cannot be estimated from the available data. Depression and or aggression. These effects are more likely to occur in children.

5.How to store Rolenium

- Keep this medicine out of the sight and reach of children.
- Store below 30°C.
- Do not use this medicine after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines if you no longer use. These measures will help to protect the environment.

6.Further information

What Rolenium contains

The active substances are fluticasone propionate and salmeterol xinafoate. Each pre-dispensed dose of **Rolenium** contains:

- 100 micrograms of fluticasone propionate and 50 micrograms of salmeterol (as salmeterol xinafoate) or
- 250 micrograms of fluticasone propionate and 50 micrograms of salmeterol (as salmeterol xinafoate) or
- 500 micrograms of fluticasone propionate and 50 micrograms of salmeterol (as salmeterol xinafoate).

The other ingredient is lactose monohydrate.

What Rolenium looks like and contents of the pack

Rolenium contains fluticasone propionate and salmeterol packed in the blisters of the single dose foil strips (double-blister strips), which are stored in the inhalation device Elpenhaler. The foil protects the powder for inhalation from the effects of the atmosphere. Each dose is pre-dispensed in one double-blister strip. Each carton box contains one inhalation device Elpenhaler with 60 double blister strips. Pack size: 60 doses

Manufacturer:

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95, Marathonos Ave., GR-19009 Pikermi, Attica
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To report any side effect(s):

- **Saudi Arabia:**

The National Pharmacovigilance and Drug Safety Centre (NPC) • Fax: +966-11-205-7662 • Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340. • Toll free phone: 8002490000 • E-mail: npc.drug@sfga.gov.sa • Website: www.sfga.gov.sa/npc
Other GCC States:
Please contact the relevant competent authority.
THIS IS A MEDICAMENT - Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you. - Follow strictly the doctor’s prescription, the method of use and the instructions of the pharmacist who sold the medicament. -The doctor and the pharmacist are the experts in medicines, their benefits and risks. - Do not by yourself interrupt the period of treatment prescribed for you. - Do not repeat the same prescription without consulting your doctor. -Keep all medicaments out of reach of children.
Council of Arab Health Ministers, Union of Arab Pharmacists