Rolenium®

Fluticasone propionate + Salmeterol

See
Asthma Control

Rolenium Elpenhaler...

More than 4,000,000 Elpenhaler treatments, satisfied patients and physicians*

- Evidence based European DPI
- Lowest error rate on critical inhalation steps[1]
- Provides better inhalation technique & more disease control[1]

Asthma: 1 inhalation twice a day (Rolenium 250 or Rolenium 500 mcg)

COPD: 1 inhalation twice a day (Rolenium 500 mcg)

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 (50+500) microgram, reduces the number of flare ups of COPD symptoms. - 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' inhaler, such as salbutamol. You should always have your fast-acting 'reliever' inhaler with you.
2. What you need to know before you use Rolenium:
Do not take Rolenium - If you are allergic to salmeterol, fluticasone propionate or to the other ingredient lactose monohydrate.
Warnings and precautions - Talk to your doctor before using Rolenium if you have: • Heart disease, including an irregular or fast heart beat, • 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 other medicines obtained without prescription. This is because Rolenium may not be suitable to be taken with some other medicines. - Tell your doctor if you are taking the following medicines, before starting to use Rolenium:* B-blockers (such as atenolol, propranolol and sotalol). B-blockers are mostly used for high blood pressure or other heart conditions. • Medicines to treat infections (such as ritonavir, ketoconazole, itraconazole and erythromycin). Some of these medicines may increase the amount of fluticasone propionate or salmeterol in your body. This can increase your risk of experiencing side effects with Rolenium, including irregular heart beats, 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, breast-feeding and fertility -If you are pregnant or breast-feeding, think you may be pregnant or are 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 - Rolenium contains 24.427 mg - 28.827 ma of lactose in each dose. This should be taken into consideration by people intolerant to lactose.
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 12 years and older with asthma • Rolenium (50+250) microgram/dose: One inhalation twice a day.
• Rolenium (50+500) microgram/dose: One inhalation twice a day.
For adults with Chronic Obstructive Pulmonary Disease (COPD) Rolenium (50+500) microgram/dose: One inhalation twice a day. - Rolenium should not be used in children below 12 years of age. - 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, nurse 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.
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 sudden-ly reduce your dose of Rolenium. This could make your breathing 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 sugar 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)
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 any of these effects or if they happen suddenly after using Rolenium, stop using Rolenium and 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 effects) -Tell your doctor if you have any of the following while taking <Product Name>, 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 are listed below:
Very common (affects more than 1 person in 10), • Headache - this usually gets better as treatment continues, • Increased number of colds have been reported in patients with COPD.
Common (affects less than 1 person in 10) - 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 anti-fungal 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 the amount of potassium in the blood (you may get an uneven heart beat, muscle weakness, cramp).
Uncommon (affects less than 1 person in 100) • 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 heart beat (tachycardia), • Feeling shaky (tremor) and fast or uneven heart beat (palpitations) - these are usually harmless and get less as treatment continues, • Chest pain. • Feeling worried (this effect mainly occurs in children), • Disturbed sleep, • Allergic skin rash.
Rare (affects less than 1 person in 1000) • Breathing difficulties or wheezing that get worse straight after taking Rolenium. If this happens stop using Rolenium inhaler. 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 heart beat or heart gives an extra beat (arrhythmias). Tell your doctor, but do not stop taking Rolenium unless your doctor tells you to stop, • A fungal infection in the oesophagus (gullet), which might take cause difficulties in swallowing.
Frequency not known, but may also occur: Depression or aggression. These effects are more likely to occur in children.

(1) Bouros D, Evangeliou MN (2016) Critical Steps: A Non-Interventional, Multicenter, Prospective, Observational Study on Critical Handling Errors with DPI Use, in Asthma and COPD Patients. J Pulm Respir Med 6: 360. doi: 10.4172/2161-105X.1000360

(2) Rolenium patient information leaflet (PIL)

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Avalon Pharma

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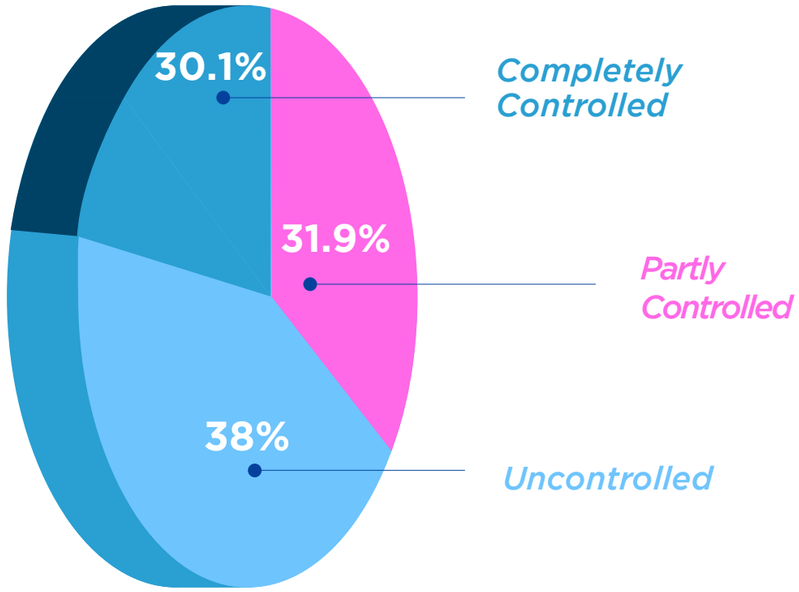
Control of bronchial asthma is still a major concern[3]

Only 30.1% of asthmatic patients in KSA have complete control[3]



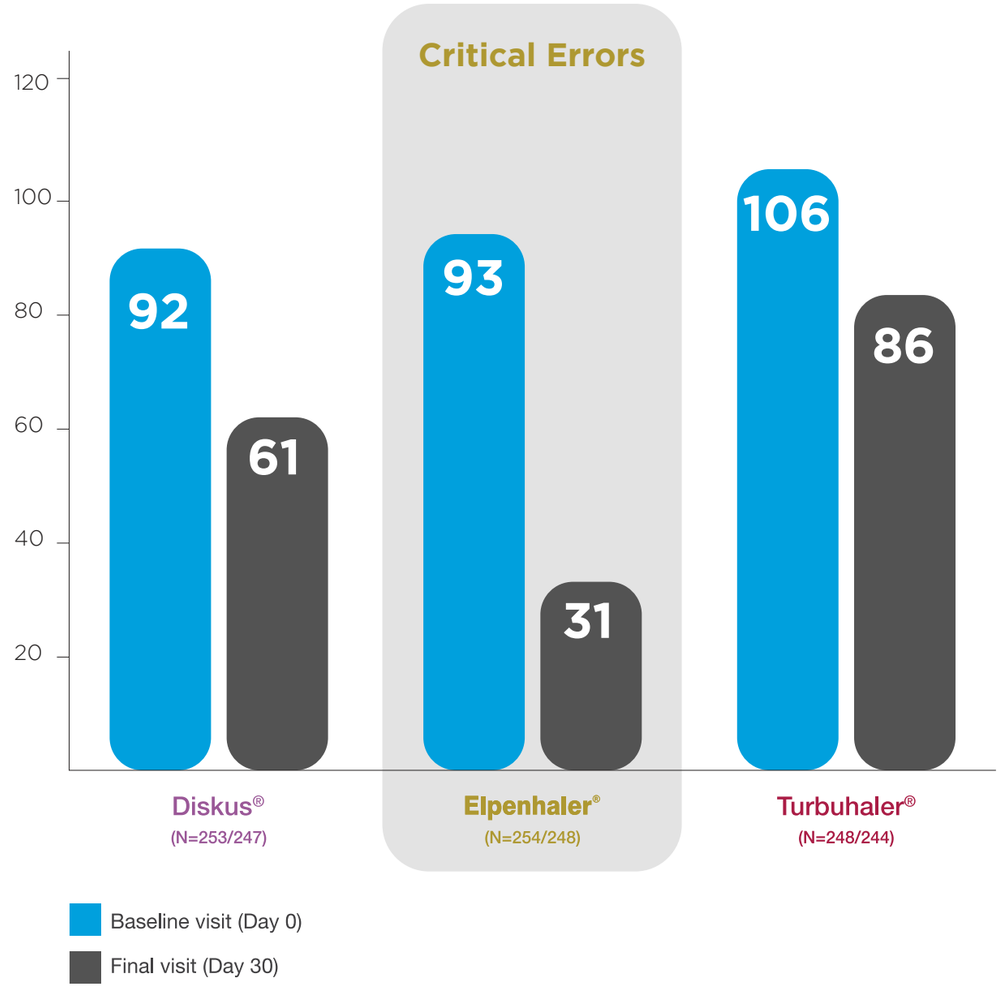
If a patient has persisting symptoms/exacerbations despite 2 – 3 months controller treatment, assess and correct the following common problems before considering any step up in treatment:[3]

- **Incorrect inhaler technique**
- Poor adherence
- Persistent exposure at home/work to asthma triggers
- Comorbidities that may contribute to respiratory symptoms and poor quality of life
- Incorrect diagnosis

(3) AL-Jahdali et al., Asthma control and predictive factors among adults in Saudi Arabia: Results from the Epidemiological Study on the Management of Asthma in Asthmatic Middle East Adult Population study. Annals of Thoracic Medicine 14(2):p 148-154, Apr–Jun 2019.
(4) Global Strategy for Asthma Management and Prevention, Global Initiative for Asthma (GINA) 2018

Rolenium Elpenhaler...

Lowest error rate on critical inhalation steps[1]



Elpenhaler Fewer critical errors at Day 30[1]

(1) Bouros D, Evangeliou MN (2016) Critical Steps: A Non-Interventional, Multicenter, Prospective, Observational Study on Critical Handling Errors with DPI Use, in Asthma and COPD Patients. J Pulm Respir Med 6: 360. doi: 10.4172/2161-105X.1000360