

Package leaflet: Information for the patient

Stalpex 50 microgram/500 microgram/dose inhalation powder, pre-dispensed Salmeterol/fluticasone propionate

Read all of this leaflet carefully before you start taking 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 Stalpex is and what it is used for
2. What you need to know before you use Stalpex
3. How to use Stalpex
4. Possible side effects
5. How to store Stalpex
6. Contents of the pack and other information

1. What Stalpex is and what it is used for

Stalpex 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), reduces the number of flare ups of COPD symptoms.

You must use Stalpex every day as directed by your doctor. This will make sure that it works properly in controlling your asthma or COPD.

Stalpex helps to stop breathlessness and wheeziness coming on. However Stalpex 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.

Stalpex should only be used to treat asthma in adults and adolescents 12 years of age and older only and adults with COPD.

2. What you need to know before you use Stalpex

Do not use Stalpex :

If you are allergic to salmeterol, fluticasone propionate or to the other ingredient lactose monohydrate.

Warnings and precautions

Talk to your doctor before using Stalpex if you have:

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

Contact your doctor if you experience blurred vision or other visual disturbances.

Children

This medicine should not be used in children younger than 12 years of age.

Other medicines and Stalpex

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 a prescription. This is because Stalpex 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 Stalpex :

- β blockers (such as atenolol, propranolol and sotalol). β blockers are mostly used for high blood pressure or other heart conditions.
- Medicines to treat infections (such as ketoconazole, itraconazole and erythromycin) including some medicines for HIV treatment (such as ritonavir, cobicistat containing products). 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 Stalpex , including irregular heart beats, or may make side effects worse. Your doctor may wish to monitor you carefully if you are taking these medicines.
- 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 breast-feeding

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

Stalpex is not likely to affect your ability to drive or use machines.

Stalpex contains lactose

Each dose of Stalpex 50 microgram/500 microgram/dose contains approximately 12.9 mg of lactose monohydrate.

The amount of lactose in this medicine does not normally cause problems in people who are lactose intolerant.

3. How to use Stalpex

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 Stalpex 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 Stalpex or reduce the dose of Stalpex without talking to your doctor first.
- Stalpex should be inhaled through the mouth into the lungs.
- You may not be able to taste or feel the powder on your tongue, even if you have used the inhaler correctly.

For adults and adolescents aged 12 years of age and older with asthma

- Stalpex 50 microgram/500 microgram/dose - One inhalation twice a day

For adults with Chronic Obstructive Pulmonary Disease (COPD)

- Stalpex 50 microgram /500 microgram /dose - One inhalation twice a day

Your symptoms may become well controlled using Stalpex 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 Stalpex for asthma, your doctor will want to regularly check your symptoms.

Your doctor will help you to manage your asthma and will adjust the dose of this medicine to the lowest dose that controls your asthma. If your doctor feels that you need a lower dose than is available from your Stalpex, your doctor may prescribe an alternative inhaler containing the same active substances as your Stalpex but with a lower dose of the corticosteroid. However, do not change the number of inhalations your doctor has prescribed without talking to your doctor first.

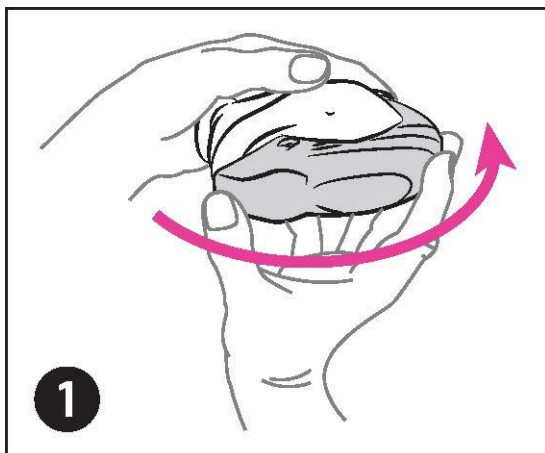
If your asthma or breathing gets worse tell your doctor straight away. You may find that you feel more wheezy, your chest feels tight more often or you may need to use more of your fast-acting 'reliever' medicine. If any of these happen, you should continue to take Stalpex but do not increase the number 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

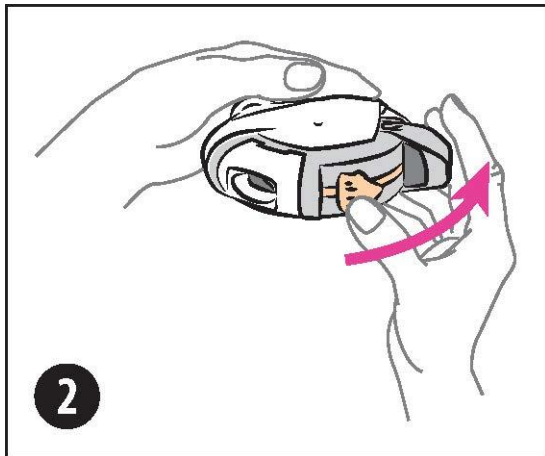
- Your doctor, nurse or pharmacist should show you how to use your inhaler. They should check how you use it from time to time. Not using Stalpex properly or as prescribed may mean that it will not help your asthma or COPD as it should.
- Stalpex device holds blisters containing salmeterol and fluticasone propionate as a powder.
- There is a counter on top of Stalpex which tells you how many doses are left. It counts down to 0.
- The numbers 5 to 0 will appear with black dot to warn you when there are only a few doses left. Once the counter shows 0, your inhaler is empty.

Using your inhaler

1. To open your Stalpex inhaler, hold the outer case in one hand and put the thumb of your other hand on the thumbgrip. Push your thumb away from you as far as it will go. You will hear a click. This will open a small hole in the mouthpiece. See picture 1.

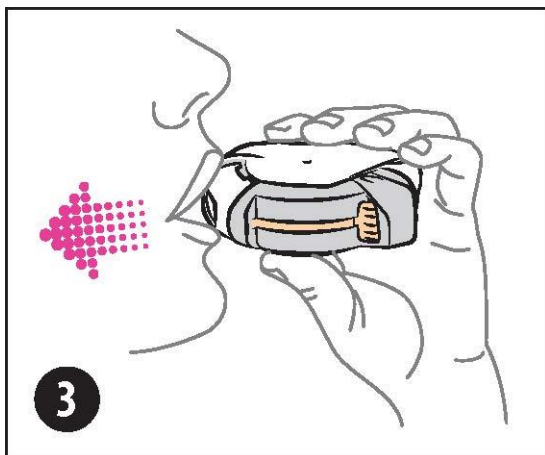


2. Hold your Stalpex inhaler with the mouthpiece towards you. You can hold it in either your right or left hand. Slide the lever away from you as far as it will go. You will hear a click. This places a dose of your medicine in the mouthpiece. See picture 2.

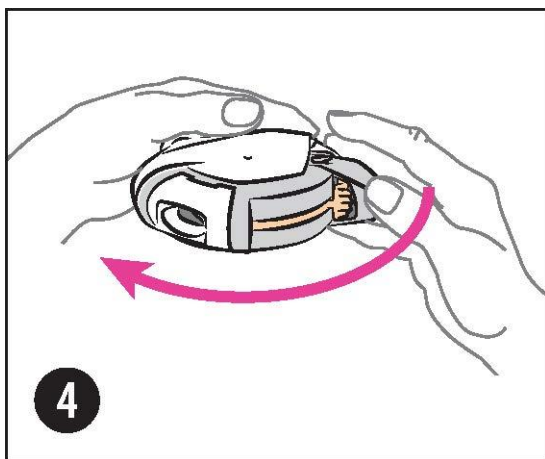


Every time the lever is pulled back a blister is opened inside and the powder made ready for you to inhale. **Do not play with the lever as this opens the blisters and wastes medicine.**

3. Hold Stalpex inhaler away from your mouth, breathe out as far as is comfortable. Do not breathe into your Stalpex inhaler.
4. Put the mouthpiece to your lips; breathe in steadily and deeply through Stalpex inhaler, not through your nose. See picture 3.
Remove Stalpex inhaler from your mouth.
Hold your breath for about 10 seconds or for as long as is comfortable.
Breathe out slowly.



5. Afterwards, rinse your mouth with water and spit it out, and/or brush your teeth. This may help to stop you getting thrush and becoming hoarse.
6. To close Stalpex inhaler, slide the thumbgrip back towards you, as far as it will go. You will hear a click.
The lever will return to its original position and is reset. See picture 4.



Your Stalpex inhaler is now ready for you to use again.

Cleaning your inhaler

Wipe the mouthpiece of Stalpex with a dry tissue to clean it.

If you use more Stalpex 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 Stalpex may reduce the amount of steroid hormones produced by the adrenal gland.

If you forget to use Stalpex

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 Stalpex

It is very important that you take your Stalpex every day as directed. **Keep taking it until your doctor tells you to stop. Do not stop or suddenly reduce your dose of Stalpex .** This could make your breathing worse.

In addition, if you suddenly stop taking Stalpex or reduce your dose of Stalpex 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).

If you have any further questions on the use of this medicine, ask your doctor, nurse 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 Stalpex to control your asthma or COPD.

Allergic reactions: you may notice your breathing suddenly gets worse immediately after using Stalpex . 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 that your heart is 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 Stalpex , stop using Stalpex and tell your doctor straight away.** Allergic reactions to Stalpex are uncommon (they affect less than 1 person in 100).

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

Tell your doctor if you have any of the following while taking Stalpex 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 (may affect more than 1 in 10 people)

- Headache - this usually gets better as treatment continues.
- Increased number of colds have been reported in patients with COPD.

Common (may affect less than 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 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 (may affect less than 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 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 adolescents).
- Disturbed sleep.
- Allergic skin rash.

Rare (may affect less than 1 in 1000 people)

- **Breathing difficulties or wheezing that get worse straight after taking Stalpex .** If this happens **stop using your Stalpex inhaler.** Use your fast-acting 'reliever' inhaler to help your breathing and **tell your doctor straight away.**
- Stalpex 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 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 Stalpex to control your asthma.

- Behavioural changes, such as being unusually active and irritable (these effects mainly occur in adolescents).
- Uneven heart beat or heart gives an extra beat (arrhythmias). Tell your doctor, but do not stop taking Stalpex unless the doctor tells you to stop.
- A fungal infection in the oesophagus (gullet), which might cause difficulties in swallowing.

Frequency not known, but may also occur:

- Depression or aggression. These effects are more likely to occur in adolescents.
- Blurred vision

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Stalpex

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Store below 30°C, in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information**What Stalpex contains**

- Each pre-dispensed dose contains 50 micrograms of salmeterol (as salmeterol xinafoate) and 500 micrograms of fluticasone propionate.
- The other ingredient is lactose monohydrate (which contains milk proteins).

What Stalpex looks like and contents of the pack

- The Stalpex contains a foil strip. The foil protects the powder for inhalation from the effects of the atmosphere.
- Each dose is pre-dispensed
- **The device/s is/are packed in cartons which hold:**
 - 1 x Stalpex containing 60 inhalations
 - 2 x Stalpex containing 60 inhalations
 - 3 x Stalpex containing 60 inhalations
 - 10 x Stalpex containing 60 inhalations

Not all pack sizes may be marketed

Marketing Authorisation Holder

Glenmark Pharmaceuticals Nordic AB
Propellergatan 2SE-211 15 Malmö
Sweden

Manufacturer

Celon Pharma S.A.
Marymoncka 15,
05-152 Kązuoł Nowy
Poland

This leaflet was last revised in March 2023.

This medicinal product is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

United Kingdom (Northern Ireland)	Stalpex 50 microgram / 500 microgram / dose inhalation powder, pre-dispensed
Romania	Salmex 50 microgramme/500 microgramme/doză pulbere de inhalat unidoză
Italy	AEROMEX
The Netherlands	Salflutin 50 microgram/500 microgram/dosis inhalatiepoeder, voorverdeeld
Ireland	Stalpex 50 microgram / 500 microgram / dose inhalation powder, pre-dispensed
Malta	Salmex 50 microgram / 500 microgram / dose inhalation powder, pre-dispensed
Luxembourg	Salmex 50 microgrammes / 500 microgrammes / dose, poudre pour inhalation en recipient unidose