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Package leaflet: Information for the user

Salflumix Easyhaler 50 microgram/250 microgram/dose, inhalation powder
Salflumix Easyhaler 50 microgram/500 microgram/dose, inhalation powder

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

1. What Salflumix Easyhaler is and what it is used for

Salflumix Easyhaler 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). Salflumix Easyhaler, at a dose of 50/500 micrograms, reduces the number of flare ups of COPD symptoms.

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

Salflumix Easyhaler helps to stop breathlessness and wheeziness coming on. However, Salflumix Easyhaler 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. What you need to know before you use Salflumix Easyhaler

Do not take Salflumix Easyhaler:

- If you are allergic to salmeterol, fluticasone propionate or to the other ingredient lactose monohydrate (which contains small amounts of milk protein).

Warnings and precautions

Talk to your doctor before using Salflumix Easyhaler if you have:

- Heart disease, including an irregular or fast heart beat
- Overactive thyroid gland
- High blood pressure
- Diabetes mellitus (Salflumix Easyhaler 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.

Other medicines and Salflumix Easyhaler

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 Salflumix Easyhaler may not be suitable to take with some other medicines.

Tell your doctor if you are taking the following medicines, before starting to use Salflumix Easyhaler:

- Beta blockers (such as atenolol, propranolol and sotalol). Beta blockers are mostly used for high blood pressure or other heart conditions.
- Medicines to treat infections (including ketoconazole, itraconazole and erythromycin and some medicines for HIV: ritonavir, cobicistat). Some of these medicines may increase the amount of fluticasone propionate or salmeterol in your body. This can increase the effects of Salflumix Easyhaler and therefore increase your risk of experiencing side effects, including irregular heartbeats. 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 Salflumix Easyhaler 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 are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

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

Salflumix Easyhaler contains lactose

Salflumix Easyhaler contains up to 17.1 milligrams of lactose in each dose. The amount of lactose in this medicine does not normally cause problems in people who are lactose intolerant. Lactose contains small amounts of milk proteins, which may cause allergic reactions.

3. How to use Salflumix Easyhaler

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 Salflumix Easyhaler every day until your doctor advises you to stop. Do not take more than the recommended dose.
- Do not stop taking Salflumix Easyhaler or reduce the dose of Salflumix Easyhaler without talking to your doctor first.
- Salflumix Easyhaler should be inhaled through the mouth into the lungs.

For asthma

Adults and adolescents aged 12 years and over

- Salflumix Easyhaler 50/250 strength- One inhalation twice a day
- Salflumix Easyhaler 50/500 strength - One inhalation twice a day

Children below 12 years of age

- Salflumix Easyhaler is not recommended for use in children below 12 years of age

For adults with Chronic Obstructive Pulmonary Disease (COPD)

- Salflumix Easyhaler 50/500 strength - One inhalation twice a day

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 Salflumix Easyhaler 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 Salflumix Easyhaler but do not increase the number of doses you take. Your chest condition may be getting worse and you could become seriously ill. See your doctor as you may need additional treatment.

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

If you forget to use Salflumix Easyhaler

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 Salflumix Easyhaler

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

In addition, if you suddenly stop taking Salflumix Easyhaler or reduce your dose of Salflumix Easyhaler 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.

The instructions how to use the inhaler are at the end of the leaflet.

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 Salflumix Easyhaler to control your asthma or COPD.

Allergic reactions: you may notice your breathing suddenly gets worse immediately after using Salflumix Easyhaler. 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 Salflumix Easyhaler, stop using Salflumix Easyhaler and tell your doctor straight away.** Allergic reactions to Salflumix Easyhaler 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 Salflumix Easyhaler, 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 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 anti-fungal medication to treat the thrush.
- Aching, swollen joints and muscle pain
- Muscle cramps.

The following common 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 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 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 (may affect up to 1 in 1,000 people)

- **Breathing difficulties or wheezing that get worse straight after taking Salflumix Easyhaler.** If this happens **stop using your Salflumix Easyhaler inhaler**. Use your fast acting 'reliever' inhaler to help your breathing and **tell your doctor straight away**.
- Salflumix Easyhaler 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 Salflumix Easyhaler 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 Salflumix Easyhaler unless the doctor tells you to stop.
- A fungal infection in the oesophagus (gullet), which might cause difficulties in swallowing.

Frequency not known (cannot be estimated from the available data), but may also occur:

- Depression or aggression. These effects are more likely to occur in children.
- 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.

5. How to store Salflumix Easyhaler

- **Keep this medicine out of the sight and reach of children.**
- Do not use this medicine after the expiry date that is stated on the carton, foil bag and label of your inhaler after EXP. The expiry date refers to the last day of that month.
- Replace Salflumix Easyhaler 1 month (50/250 strength) or 2 months (50/500 strength) after you opened the foil bag. Write down the date you opened the bag to help you remember.
- After opening the foil bag do not store above 30°C and store protected from moisture. Keep the inhaler in its protective cover when not in use.
- If your Salflumix Easyhaler gets damp you need to replace it with a new one.
- 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 to protect the environment.

6. Contents of the pack and other information

What Salflumix Easyhaler contains

- Each dose contains salmeterol xinafoate equivalent to 50 micrograms of salmeterol and 250 or 500 micrograms of fluticasone propionate.
- The other ingredient is lactose monohydrate (which contains milk proteins).

What Salflumix Easyhaler looks like and contents of the pack

Salflumix Easyhaler is an inhaler containing your medicine. The inhalation powder is white. Each inhaler has a white body with purple upper part.

Each inhaler contains 60 doses. The multidose powder inhaler is sealed in a foil bag and packed with or without a protective cover in a cardboard box. If you need a new protective cover, please contact the Product Registrant (details given below).

Salflumix Easyhaler is available in packs of 1 inhaler.

Marketing Authorisation Holder

Product registrant:
Orion Pharma (SG) Pte Ltd

Manufacturer

Orion Corporation Orion Pharma
Orionintie 1
FI-02200 Espoo
Finland

Detailed and updated information on this product is available by scanning this QR code (included also on outer carton and inhaler label) with a smartphone. The same information is also available on the following URL: <https://www.oeh.fi/sfas>

QR code to <https://www.oeh.fi/sfas>

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How to use the Easyhaler inhaler

About your Easyhaler

Salflumix Easyhaler may be different to inhalers you have used in the past. Therefore it is very important that you use it properly as using incorrectly can lead to you not receiving the right amount of medicine. This could make you very unwell or could lead to your asthma and COPD not being treated as it should.

Your doctor, nurse or pharmacist will show you how to use your inhaler properly. Make sure you understand the correct way to use the inhaler. If you are unsure contact your doctor, nurse or pharmacist. As with all inhalers, caregivers should ensure that children prescribed Salflumix Easyhaler use correct inhalation technique, as described below. You can also use the instruction video at <https://www.oeh.fi/sfas>

When you first get your Easyhaler

The Easyhaler comes in a foil bag. Do not open the foil bag until you are ready to start using the medicine as it helps to keep the powder dry in the inhaler.

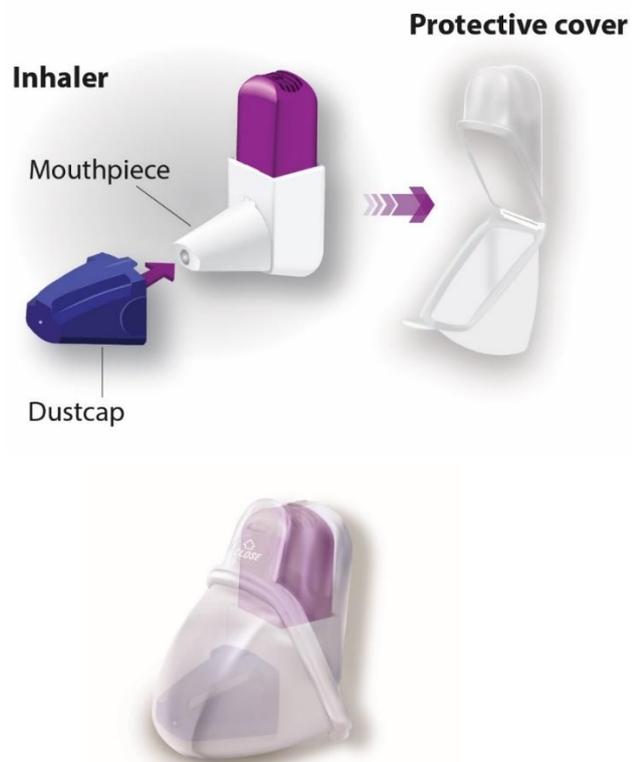
When you are ready to start treatment open the bag and record the date e.g. in your calendar.

Use the inhaler within 1 month (50/250 strength) or 2 months (50/500 strength) of removing from the foil bag.

Insert your inhaler in the protective cover. When you insert your inhaler in the protective cover make sure the dustcap is on the inhaler, as this stops it going off by accident. Make sure the protective cover is properly closed. This helps to improve durability of the product.

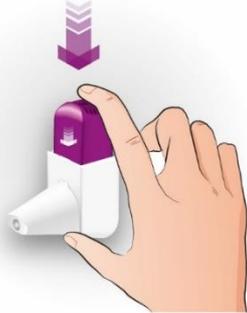
You can use the inhaler with or without the protective cover. Follow the instructions below.

You must store the inhaler in its protective cover when not in use.



HOW TO USE CORRECTLY

Using the Easyhaler without a protective cover

<p>Step 1: SHAKE</p> <ul style="list-style-type: none">• Remove the dustcap• Shake the inhaler 3 to 5 times holding it in the upright position	<p>SHAKE x 3-5</p> 	<p>Important points to remember</p> <ul style="list-style-type: none">• It is important to keep the inhaler in the upright position• If you accidentally click while you shake the inhaler, empty the powder from the mouthpiece as shown below
<p>Step 2: CLICK</p> <ul style="list-style-type: none">• Keep holding the inhaler upright between your forefinger and thumb• Press down until you hear a click, and let the inhaler click back again. This releases a dose• Only click down once	<p>CLICK x 1</p> 	<p>Important points to remember</p> <ul style="list-style-type: none">• The inhaler will not click if the dustcap is still on• Only click down once• If you accidentally click more than once, empty the powder from the mouthpiece, see below• Click to release dose before you inhale, not at the same time• Keep the inhaler upright when you click it and when you inhale the dose. If you tip it, the powder could fall out before you are able to inhale it

<p>Step 3: INHALE</p> <ul style="list-style-type: none"> • Keep holding the inhaler upright • Breathe out normally • Place the mouthpiece in your mouth between your teeth and close your lips tightly around the mouthpiece • Take a strong and deep breath in • Take the inhaler out of your mouth, hold breath for at least 5 seconds, then breathe out normally. • After you have taken the dose, 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. 	<p style="text-align: center;">INHALE</p> 	<p>Important points to remember</p> <ul style="list-style-type: none"> • Make sure the whole mouthpiece is well inside your mouth, so that the medication gets into your lungs • Make sure your lips make a good seal around the mouthpiece • Do not breathe out into the inhaler. This is important: it could clog up the inhaler. If you breathed out into the inhaler, empty the powder from mouthpiece, see below
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<p>Step 4: STORE</p> <p>After you have used the inhaler</p> <ul style="list-style-type: none"> • Put the dust cap back on the mouthpiece, as it prevents the inhaler going off by accident. • You must store the inhaler in its protective cover when not in use. • Make sure the cover is properly closed.

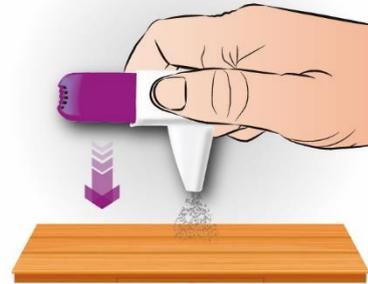
Using the Easyhaler with a protective cover

<p>Open the protective cover and remove the dustcap, then follow the same instructions as above</p> <ol style="list-style-type: none"> 1. Shake 2. Click <ul style="list-style-type: none"> • Keep the inhaler in the upright position when clicking it 3. Inhale 4. Store <ul style="list-style-type: none"> • Put the dust cap back on the mouthpiece. • Close the protective cover. • Make sure the cover is properly closed. 	
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How to empty the powder from the mouthpiece

If you click the inhaler by accident, or if you might have clicked it more than once, or if you breathe out into it, empty the mouthpiece.

- Tap the mouthpiece to empty the powder onto a table top, or the palm of your hand.
- Then start again with steps Shake-Click-Inhale.



Cleaning the Easyhaler

Keep your inhaler dry and clean. If necessary you may wipe the mouthpiece of your inhaler with a dry cloth or tissue. Do not use water: the powder in the Easyhaler is sensitive to moisture.

When to switch to a new Easyhaler

The dose counter shows the number of remaining doses. The counter turns after every 5th click. When the dose counter starts turning red, there are 20 doses left.

If you do not already have a new Easyhaler, contact your doctor for a new prescription. When the counter reaches 0 (zero), you need to replace the Easyhaler.

If you use the protective cover, you can keep it and insert your new inhaler into it.



Remember

- **1. Shake – 2. Click – 3. Inhale – 4. Store**
- After you have taken the dose, rinse your mouth with water and spit it out and/or brush your teeth.
- Do not get your inhaler wet, protect it from moisture.

If you have any further questions on the use of this product, ask your doctor or pharmacist.