

**Package insert in accordance with the Pharmacists Regulations**

**(Preparations) 1986**

The medication is marketed by doctor's prescription only

**Flusalmer S.K. 50/250 mcg**

**Flusalmer S.K. 50/500 mcg**

Each dose contains 50 micrograms Salmeterol as Xinafoate/250 micrograms Fluticasone propionate as powder for inhalation.

Each dose contains 50 micrograms Salmeterol as Xinafoate/500 micrograms Fluticasone Propionate as powder for inhalation.

For the list of excipients and allergens please refer to section 2 - "Important information on some of the drug's ingredients" and section 6 - "Additional information."

**Read the insert carefully in its entirety before using the medication.** This insert contains concise information on the medication. If you have further questions, refer to the doctor or pharmacist.

This medication was prescribed for you. Do not pass it on to others. It might harm them even if it seems to you that their medical condition is similar.

**1. What is the medication for?**

Flusalmer S.K. contains two active agents: Salmeterol and Fluticasone propionate:

- Salmeterol is a long-acting bronchodilator. Bronchodilators help the airways in the lungs to remain open. It makes it easier for air to go in and out. The effect lasts at least 12 hours.
- Fluticasone propionate is a corticosteroid that alleviates swelling and irritation in the lungs.

The doctor has prescribed this medication to help prevent respiratory problems such as:

- Asthma
- COPD - Flusalmer S.K., at a dosage of 50/250 and 50/500 micrograms is also intended for the treatment of chronic obstructive pulmonary disease (COPD) and reduces the number of COPD symptom flare-ups.

You should use Flusalmer S.K. daily as instructed by your doctor. This will guarantee its proper activity in controlling your asthma or COPD.

**Flusalmer S.K. helps prevent future dyspnea and wheezing. However, Flusalmer S.K. is not to be used to relieve a sudden episode of dyspnea or wheezing. If this happens, you must use a quick relief inhaler, such as Salbutamol. You must always carry a quick relief inhaler.**

**Therapeutic group**

Salmeterol is a beta-2 receptor agonist.

Fluticasone propionate is a corticosteroid.

## **2. Before using the medication**

### **Do not use the medication:**

If you are sensitive (allergic) to salmeterol, fluticasone propionate or the excipient lactose monohydrate that the drug contains

As specified in section 6.

### **Special warnings concerning use of the medication**

Prior to treatment with Flusalmer S.K., tell your doctor if you have:

- Heart disease, including irregular or fast heart rate
- Hyperthyroidism
- Hypertension
- Diabetes (Flusalmer S.K. might raise glucose levels in your blood)
- Low potassium in your blood
- Present or past tuberculosis (TB) or other lung infections

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

### **Children and adolescents**

- The preparation is not intended for use in children under the age of 12 years.

### **Drug-drug interactions/reactions**

If you are taking or have recently taken other medications, including asthma medications, over-the-counter medications and nutritional supplements, tell the doctor or pharmacist.

**This is because Flusalmer S.K. might not be suitable to be taken together with a number of other medications.** In particular, inform the doctor or pharmacist if you take:

- Beta-blockers, (such as: atenolol, propranolol, sotalol). Beta-blockers are used primarily to treat high blood pressure or other cardiac conditions.
- Medications to treat infections (such as: ketoconazole, itraconazole and erythromycin), including certain medications to treat HIV infection (such as: ritonavir and other drugs containing cobicistat). Some of these drugs might raise the amount of fluticasone propionate or salmeterol in your body. This can increase your risk to experience side effects with Flusalmer S.K., including irregular heart rate, or might exacerbate the side effects. Your doctor may want to carefully monitor your condition if you take these drugs.
- Corticosteroids (oral or injected). If you have recently taken these medications, it might increase the risk that this medication will affect your adrenal.
- Diuretics, used to treat high blood pressure.
- Other bronchodilators (such as salbutamol).
- Xanthines, these medications are often used to treat asthma.

### **Pregnancy, breastfeeding and fertility**

If you are pregnant, planning to conceive or breastfeeding, consult the doctor or pharmacist before using the medication.

### **Driving and using machinery**

It is unlikely that Flusalmer S.K. will affect your ability to drive or use machinery.

**Important information on some of the ingredients of the medication** Flusalmer S.K. Contains up to 24.8 milligrams of lactose monohydrate in each dose. The amount of lactose in this medication does not normally cause problems in people with lactose intolerance. The excipient lactose monohydrate contains small quantities of milk proteins, which might cause allergic reactions.

### **3. How will you use the drug?**

Always use the preparation as instructed by the doctor. Check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the preparation. Use your Flusalmer S.K. every day, until your doctor instructs you to stop. Do not exceed the recommended dosage.

Do not stop taking Flusalmer S.K. or decrease the dosage without first talking to your doctor.

Inhale Flusalmer S.K. through the mouth into the lungs.

The dosage and the manner of treatment will be determined by the doctor only. The standard dosage is usually:

#### **For asthma**

##### **Adults and children 12 years of age and older**

- Flusalmer S.K. 50/250 - one inhalation twice a day.
- Flusalmer S.K. 50/500 - one inhalation twice a day.

##### **Children under the age of 12 years**

- Flusalmer S.K. is not intended for use in children under the age of 12 years. There are other treatment options available for this age range. Please consult the attending doctor.

##### **For adults with chronic obstructive pulmonary disease (COPD)**

- Flusalmer S.K. 50/250 - one inhalation twice a day.
- Flusalmer S.K. 50/500 - one inhalation twice a day.

Your symptoms may be well under control while using Flusalmer S.K. twice a day. If so, your doctor may decide to reduce your dosage to once a day. The dosage can change to:

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

It is very important to follow your doctor's instructions on the number of inhalations to be taken and how frequently to take your drug.

#### **Do not exceed the recommended dose**

If you are using Flusalmer S.K. for asthma, your doctor will want to check your symptoms regularly.

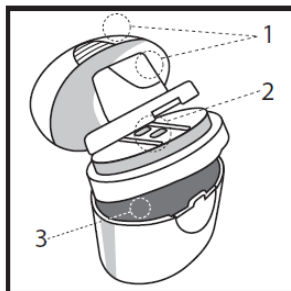
**If your asthma or respiration deteriorate** chills, **tell your doctor immediately**. You may feel that you wheeze more, feel chest pressure more often, or that you need to use a quick relief medication more. If one of these happens, you should continue taking Flusalmer S.K., but do not increase the number of inhalations that you take. Your chest condition may be worsening, and you might be seriously ill. See your doctor, since you may need additional treatment.

### Instructions for use

- Your doctor, nurse or pharmacist will show you how to use your inhaler. They have to occasionally check how you use it. The meaning of using Flusalmer S.K. incorrectly or not as you were prescribed might be that it will not help your asthma or COPD as it should.

### Description of the inhaler

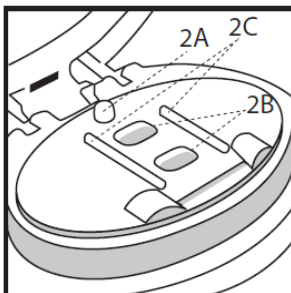
The inhaler is used for the inhalation of two medications at the same time, supplied in powder form, for inhalation in fixed doses. Each drug is packed separately from the other in one of two caplets in a specially designed double aluminum strip, the two-caplet strips are stored inside the inhaler.



Then inhaler is composed of 3 parts:

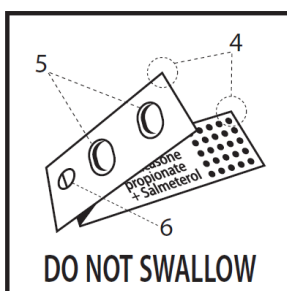
- The nozzle and cap **(1)**.
- A surface **(2)** where the two-caplet strip is placed (medication support surface).
- A storage container **(3)** that contains the two-caplet strips.

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



The medication support surface contains:

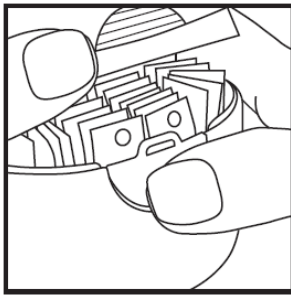
- An anchoring point **(2A)** to which the two-caplet strip connects.
- Two spaces **(2B)** that store the two caplets in the strip.
- Two guiding lines **(2C)** that firmly secure the two-caplet strip on the right place on the medication support surface.



The two-caplet strip contains:

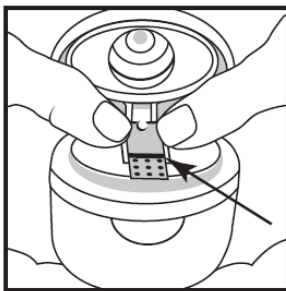
- Two aluminum sheets **(4)**.
- Two caplets **(5)**, one containing the medication fluticasone propionate and the other containing the medication salmeterol.
- Pinhole **(6)**

## Using your inhaler



### 1. Preparing the inhaler

Open the storage container by pressing as shown in the illustration, take a strip and close the storage container again.



Expose the nozzle completely by applying moderate pressure on the area of the lines.

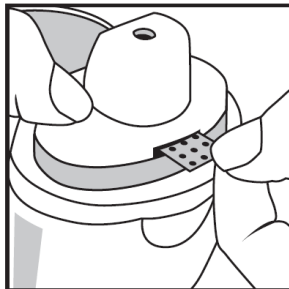
Open the lock and push the nozzle back to expose the medication support surface.

Hold the two-caplet strip with the shiny side facing up, so that you can see the blue stripe, as shown by the arrow in the illustration.

The strip's marked part should face downwards.

Place the pinhole in the strip on the anchoring point on the medication support surface. Apply light pressure to make sure that the strip is well connected on the anchoring point.

The two caplets in the strip will integrate into the spaces in the medication support surface, and the guiding lines will secure the strip in the correct position.



Close the inhaler nozzle, and horizontally pull out the tip of the strip that is sticking out until it tears off.

The dose is now ready for inhalation.

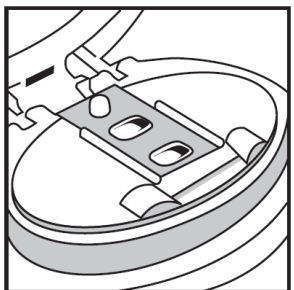
### 2. Inhaling the dose

Hold the inhaler away from your mouth. Blow out as long as you feel comfortable. Be careful not to blow into the inhaler nozzle. Bring the inhaler to your mouth and firmly tighten your lips around the inhaler nozzle.



Breathe slowly and deeply from your mouth (and not your nose) until your lungs are full.

Hold your breath for 5 seconds or as long as you can do so comfortably, and at the same time, remove the inhaler from your mouth. Breathe out and continue breathing normally.



Open the inhaler nozzle. You will see that you have inhaled all the powder and that the strip's caplets are empty.

Remove the empty strip and continue to step 3 - cleaning your inhaler.

**Afterwards, rinse your mouth with water and spit them out and/or brush your teeth. Doing this can help prevent oral thrush and hoarseness.**

As with other inhalers, the caregiver needs to make sure that children taking Flusalmer S.K. use the correct inhalation technique, as described above.

### **3. Cleaning your inhaler**

After each use, wipe the inhaler nozzle and the medication support surface with a dry cloth or dry tissue paper in order to clean the inhaler. Do not use water to clean the inhaler. Close the nozzle and cap.

**If you have accidentally taken a higher dose** It is important to use the inhaler as instructed. If you have accidentally taken a dose larger than recommended, talk to your doctor or pharmacist. You may notice that your heart is beating faster than usual and a sensation of unsteadiness. You may also have dizziness, headache, muscle weakness and joint pains.

If you have been using larger doses for a long time, you should consult your doctor or pharmacist. This is because large doses of Flusalmer S.K. might decrease the amount of steroid hormones produced by the adrenal.

If you have taken an overdose or if a child has accidentally swallowed some of the medication, proceed immediately to a doctor or hospital emergency room and bring the medication package with you.

### **If you forgot to take the medication**

If you forgot to take this medication at the required time, do not take a double dose. Take the next dose on its regular time and consult the doctor.

Be sure to adhere to the treatment as recommended by the doctor.

### **If you stop taking the medication**

It is very important that you use your Flusalmer S.K. every day as you were instructed. Continue **to use it until your doctor tells you to stop. Do not suddenly stop or decrease your dose of Flusalmer S.K.** It might cause a deterioration of your respiration.

In addition, suddenly stopping the use of Flusalmer S.K., or decreasing the dose of Flusalmer S.K. might cause (very rarely) problems in your adrenal (adrenal insufficiency), which might sometimes cause side effects.

These side effects can include any of the following:

- Abdominal pain
- Fatigue and loss of appetite, malaise
- Nausea and diarrhea
- Weight loss
- Headache or drowsiness
- Low levels of glucose in your blood
- Low blood pressure and seizures

When your body is in stress such as fever, trauma (such as a traffic accident), infection or surgery, adrenal insufficiency can exacerbate, and you might have any of the side effects listed above.

If you notice any side effects, speak to the doctor or pharmacist. To prevent the occurrence of these symptoms, your doctor may prescribe for your additional corticosteroids in tablet form (such as prednisolone).

- **Do not take medications in the dark! Check the label and dose every time you take a medication. Wear glasses if you need them.**

**If you have further questions on using the medication, consult a doctor or pharmacist.**

## **4. Side effects**

As with any drug, use of Flusalmer S.K. might cause side effects in some users. Do not be alarmed to read the list of side effects. You may not experience any of them. To reduce the chance of side effects, your doctor will prescribe the lowest dose of Flusalmer S.K. to control your asthma or COPD.

**Allergic reactions: You might notice a sudden deterioration in your breathing immediately after using Flusalmer S.K.** You might be very wheezy and cough or experience dyspnea. You might also notice itching, rash (itchy bumps) and swelling (usually of the face, lips, tongue or throat) or you might suddenly feel that your heart is beating very fast or you feel you are lightheaded or dizzy (which can result in collapse or loss of consciousness). **If you suffer from any of these effects or if they occur suddenly after using Flusalmer S.K., stop using Flusalmer S.K. and contact the doctor immediately.** Allergic reactions to Flusalmer S.K. are not common (they affect less than 1 person out of 100).

### **Pneumonia in COPD patients (a common side effect)**

**Tell your doctor** if you feel one of the following effects while using Flusalmer S.K. These can be symptoms of pneumonia:

- Fever or chills
- Increased production of sputum, change in sputum color
- Increased cough, exacerbation of breathing difficulties

Other side effects are listed below:

**Very common side effects (appear in more than 1 person out of 10)**

- Headache - usually gets better as treatment continues.
- A larger number of common colds was reported among COPD patients.

**Common side effects (appear in less than 1 person out of 10)**

- Oral thrush (painful, raised cream-yellow colored spots) in the mouth and throat. In addition, pains in the tongue, hoarseness and irritation in the throat. Rinsing your mouth with water and spitting them out immediately and/or brushing your teeth after taking each dose of your drug may help. Your doctor may prescribe an antifungal medication to treat oral thrush.
- Painful and swollen joints and muscle pains.
- Muscle cramps.

The following side effects were also reported in patients with chronic obstructive pulmonary disease (COPD):

- Bruises and fractures.
- Sinusitis (sensation of pressure or congestion in the nose, cheeks and behind the eyes, sometimes with a pulsating pain).
- Reduced amount of potassium in the blood (you may feel irregular pulse, muscle weakness, cramps).

**Uncommon side effects (appear in less than 1 person out of 100)**

- Increased amount of sugar (glucose) in your blood (hyperglycemia). If you have diabetes, more frequent monitoring of blood glucose may be necessary, and possibly an adjustment of your regular treatment for diabetes.
- Cataract (cloudy eye lenses).
- Very fast pulse (tachycardia).
- Sensation of unsteadiness (tremor) and rapid or irregular pulse (palpitations) - these are usually harmless and become less frequent as treatment continues.
- Chest pain.
- Sensation of worry (this effect occurs primarily in children).
- Sleep disorders.
- Allergic skin rash.

**Rare side effects (appear in less than 1 person out of 1000)**

- **Breathing difficulties or wheezing that worsen immediately after using Flusalmer S.K.** If this happens **stop using your Flusalmer S.K.** Use your quick relief inhaler to help you breathe **and tell your doctor immediately.**
- Flusalmer S.K. might affect the normal production of steroid hormones in the body, particularly if you have been taking large doses for a long time. The effects include:
  - Slowed growth in children and adolescents
  - Reduced bone density
  - Glaucoma
  - Weight gain
  - Rounded face (moon face) (Cushing's syndrome)Your doctor will examine you regularly for each of these side effects and will make sure that you take the lowest dose of Flusalmer S.K. to control your asthma.
- Changes in behavior, such as if you are unusually active and become irritated quickly (these effects occur predominantly in children).



- Irregular pulse or additional heartbeat (arrhythmia). Tell your doctor, but do not stop taking Flusalmer S.K. unless the doctor tells you to stop.
- Fungal infection in the esophagus, which might cause swallowing difficulties.

#### **Side effects of unknown frequency, but which may also occur**

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

**If a side effect appeared, if one of the side effects exacerbates, or when you experience a side effect that was not mentioned in the insert, please consult a doctor.**

#### Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking the link “Reporting side effects due to pharmaceutical treatment” on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that refers to the online form for reporting side effects, or by clicking the link: <https://sideeffects.health.gov.il/>

### **5. How to store the medication?**

- Prevent poisoning! This and any other medication must be kept in a closed place out of the sight and reach of children and/or infants, thereby preventing poisoning. Do not induce vomiting without explicit instruction from the doctor.
- Do not use the medication after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store at a temperature below 25°C.

### **6. Additional information**

- **In addition to the active ingredients, the medication also contains** - lactose monohydrate (which contains milk proteins).
- **The medication’s appearance and package contents** -

Each medication (fluticasone propionate and salmeterol) is packed separately in one of two caplets in strips of a single measured dose (two-caplet strip).

Each box contains one inhaler with 60 two-caplet strips.

60 doses per package.

- Marketing Authorization Holder: K.S. Kim International Ltd., 94 Yigal Alon Street, Tel-Aviv-Yaffo, 6789139.
- **Manufacturer:** Elpen Pharmaceutical Ltd., Attica, Greece
- Medication’s registration number in the State Drug Registry at the Ministry of Health:  
50/250 mcg 164-50-35043-00  
50/500 mcg 164-51-35044-00

For the sake of simplicity and for convenience of reading, this insert was written in the male pronoun. However, the medication is intended for both genders.

Edited May 2020

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