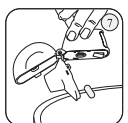


5. Breathe out fully.

Important: Please do not breathe into the mouthpiece at any time.



6. Place the mouthpiece in your mouth and tilt your head slightly backwards. Close your lips around the mouthpiece and breathe in as quickly and as deeply as you can. As you breathe in, you will inhale the medicine into your lungs. You should hear the capsule spinning in the inhaler. If you do not hear this whirring noise, the capsule may be stuck in the compartment. If this occurs, open the inhaler and loosen the capsule by prising it out of the compartment. Do not try to loosen the capsule by repeatedly pressing the buttons. If you have heard the whirring noise, hold your breath for as long as you comfortably can while taking the inhaler out of your mouth. Then breathe normally. Open the inhaler to see if any powder is still in the capsule. If there is still powder in the capsule repeat steps 5 and 6.



7. Open the mouthpiece again. Turn the device and discard the used capsule. If you need to clean the inhaler, wipe the mouthpiece and capsule compartment with a dry cloth or a clean soft brush. Close the mouthpiece and powder cap and leave your device.

NOTE: **DO NOT** use water to clean the inhaler.

The capsules should not be exposed to extreme temperatures.

Roveflu contains a small amount of a powder, therefore capsules is only partially filled.

#### Questions and Answers Related to the Administration

1. How can I prevent the capsules from breaking into small particles? During using the device, capsules can break and small particles can escape into your mouth or throat while you are breathing. You can prevent this by applying the following:

- Keep capsules in the original packaging (blister packs) before using.
- Store capsules at room temperature below 25 ° C.
- Protect capsule from moisture.

2. Are capsule particles harmful?

No. Capsule is made of edible gelatin which is harmless to human gelatin particles escaping from your mouth or throat could be swallowed.

3. How can I remove the capsule that is stuck in the capsule reservoir? Open the device, turn it upside down and gently tap the bottom.

4. How can I be sure that I really take the dose or not?
- You will detect the vibrates of capsule when you breathe.
  - You will feel 'sugar taste' in your mouth caused by lactose. You can feel the powder on the back your throat. This is normal.
  - The capsule will be empty when the dose is taken.

5. How can I clean the powder remaining inside the device?

- Use a dry cloth or a soft brush
- You should not forget that you should never wash the device.

#### Different age groups

##### Use in children:

4-12-year-old children should use capsules containing Roveflu 50/100 micrograms of powder for inhalation. There is no information regarding use of Roveflu in children younger than 4-year-old.

##### Use in elderly:

No dose adjustment is required in the elderly.

##### Special usage

##### Renal / Liver failure:

Formal pharmacokinetic studies using this medicine, have not been conducted in patients with hepatic or renal impairment. However, since both fluticasone propionate and salmeterol are predominantly cleared by hepatic metabolism, impairment of liver function may lead to accumulation of fluticasone propionate and salmeterol in plasma. Therefore, patients with hepatic disease should be closely monitored.

*If you have the impression that the effect of Roveflu is too strong or too weak, talk to your doctor or pharmacist.*

##### If you take more Roveflu than you should:

*If you may have taken more Roveflu than you should, talk to a doctor or pharmacist.*

##### If you forget to take Roveflu

If you forget to use Roveflu, continue taking the next dose at your regular time.

*Do not take a double dose to make up for forgotten individual doses.*

##### If you stop taking Roveflu

Roveflu treatment should not be stopped abruptly in patients with asthma exacerbation; treatment dose should be reduced gradually under the supervision of a doctor. This may worsen your respiratory problems and can rarely cause serious side effects.

The effects are listed above:

- Stomach ache
- Fatigue and loss of appetite
- Nausea and diarrhea
- Weight loss
- Headache and dizziness
- Reduction in potassium levels in your blood
- Low blood pressure and seizures

Symptomatic decompensation in patients with COPD may occur following the cessation of therapy (may result in organ failure); treatment should be discontinued under a physician supervision.

#### 4. Possible side effects

Like all medicines, Roveflu may cause side effects in some patients who are sensitive to the substances contained in Roveflu. To reduce possibility of side effects, your doctor will prescribe lowest possible dose of Roveflu to control your asthma

##### Very common (affects more than one in 10 patients):

- Headache - this usually recovers with the continuation of the treatment.
- Increase in number of colds has been reported that in patients with COPD.

##### Common (affects less than one in 10 patients):

- Aphthae in mouth and throat (sore, creamy-yellow fluffy spots). In addition swelling in tongue and throat and hoarseness may occur. After each inhalation rinse your mouth with water and spit the water immediately. Your doctor may prescribe an anti-fungal medication
- Tremor and fast or irregular heartbeat (palpitations) - these are harmless generally decreases as you continue treatment.
- Muscle cramps.

Chronic Obstructive Pulmonary Disease (COPD) patients reported the following side effects:

- Pneumonia and bronchitis (lung infection): Tell your doctor if you notice any of the following symptoms: increased sputum production, change in sputum color, fever, chills, increased cough, and increased breathing problems.
- Decay and bone fractures.
- Sinusitis (tightness or fullness in the nose, cheeks and behind the eyes, sometimes accompanied by a throbbing pain.)
- Decrease in blood potassium levels (your heartbeat can become irregular, can weaken your muscles and cramps.).

##### Uncommon (affects less than one in 100 patients):

- Rash.
- Very fast heartbeat (tachycardia).
- Decrease in blood potassium levels (may cause irregular heartbeat, weaken your muscles and develop cramps.).

##### Very rare (affects less than one in 10,000 patients):

- Allergic reactions: you may notice suddenly worsen of your respiration after using Roveflu. You may experience viable wheezing and coughing. In addition, itching and swelling of your body may occur (usually the face, lips or throat area). If you experience these effects, stop using Roveflu, **notify your doctor IMMEDIATELY or contact your nearest hospital emergency department.**

If you use high doses of Roveflu especially for long periods of time, may affect the normal production of steroid hormones in the body. These possible effects are as follows:

- Slowdown of growth in Children and adolescents.
- Thinning of the bones.
- Cataract and glaucoma.
- Weight gain.
- Rounded (moon shaped) face (Cushing's syndrome).

Your doctor will check you regularly to investigate the presence of these side effects and will help you get the lowest possible dose of Roveflu to control your asthma

- Irregular heartbeat (arrhythmia). Notify your doctor, but do not stop the medication until your doctor recommends you.

- Increase in amount of your blood sugar (glucose) (hyperglycemia). If you have diabetes you may need to monitor your blood sugar more often and probably need to be adjusted in your usual diabetes treatment.

- Anxious mood, sleep disturbances and unusual changes in behavior, such as the active or being irritable (these effects can be seen usually in children).

- Painful, swollen joints and muscle pain.

*If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.*

##### 5. How to store Roveflu?

*Keep in the original package and out of the reach and sight of children.*

Store Roveflu at room temperature below 25 °C and in a dry place.

##### Use it properly accordance to the expiry date

*Do not use Roveflu after the expiry date on the packaging.*

Do not use Roveflu if you notice defects in the product and / or packaging.

##### Marketing Authorisation Holder and Manufacturer:

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