

Roveflu[®] 50/500 mcg Capsair
capsules powder inhalation

- **Active substances:** Each capsule containing powder for inhalation contains 50 mcg salmeterol (as salmeterol xinafoate) and 500 mcg fluticasone propionate.
- **Excipient(s):** Lactose. (from cow's milk)

What is in this leaflet:

- 1. What Roveflu is and what it is used for?**
Roveflu contains salmeterol and fluticasone as active substances.

Fluticasone belongs to group of medicines called corticosteroids and because of inflammation relieving effect, leads to reduction in swelling and tenderness of walls of airways in the lungs relieving breathing problems.

Rovellu is used in the following conditions:

2. What you need to know before you take Roveflu
DO NOT take Roveflu
If:

1. you are allergic (hypersensitive) to active substances, salmeterol or fluticasone, or to excipient lactose...
2. You are in primary treatment of status asthmatic or acute episodes of asthma or COPD requiring intensive measures.
3. You have severe hypersensitivity to milk proteins.

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- Tell your doctor if you use any medications you use for such situations.
- **Tell your doctor if you increased the use of short-acting bronchodilator to resolve symptoms (bronchodilators), this indicates worsened of your asthma.**
- Inform your doctor if your asthma worsened suddenly and in a progressive manner.
- **Do not stop your medication without consulting your doctor** Roflumilol may be discontinued gradually under the supervision of your doctor.
- COPD patients using Roflumilol (pneumonia) have an increased possibility of development of pneumonia
- Inform your doctor if you have active and silent pulmonary tuberculosis while on the treatment.
- Inform your doctor if you have thyrotoxicosis (excess hormone secretion caused by the state of the thyroid gland), your doctor may want to change your treatment.
- If you have a significant increase in high blood pressure and heart rate when administered in doses higher than therapeutic doses, so tell your doctor if you have any cardiovascular disease, your doctor may wish to change your treatment.
- Roflumilol especially when administered in doses higher than therapeutic doses may lead to a decrease in potassium levels in the blood, so tell your doctor if the potassium level in your blood is low or if you are prone to such a condition, your doctor may wish to lower your treatment.
- Roflumilol especially when used in high doses for a long time, may cause side effects such as Cushing's syndrome (like a hump on the back, fat accumulation, so rounding, excessive hair growth and bone resorption, particularly in the lower back and pelvis) Cushing-like symptoms, adrenal suppression (suppression of the release of hormones from the adrenal glands), osteoporosis (bone loss) in children and adolescents, decrease in bone mineral density, cataract and glaucoma (eye pressure) because it contains corticosteroids.
- It can lead to growth retardation in children and adolescents so height and weight on Roflumilol treatment for a long time should be monitored regularly.
- Some patients may be more sensitive to inhaled (taken by breathing) corticosteroids so your doctor will closely monitor you if you switched to Roflumilol.
- After starting inhaled fluticasone propionate therapy to carry with you a warning card indicating that require additional treatment in periods of stress.
- Roflumilol may increase the level of blood sugar, please inform your doctor if you have diabetes, your doctor may wish to change your treatment.
- If you are using ritonavir (a medicine used against the virus), inform your doctor.
- Your doctor may want you to follow during the first 3 months of your treatment for possible asthma-related side effects.

Please consult your doctor if these warnings apply to you, even at any time in the past.

There is no interaction with food and drink because of the route of administration.

Pregnancy category C. Consult your doctor or pharmacist before using this medication.

If you are pregnant and you are planning to become pregnant, tell your doctor

If you notice that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Consult your doctor or pharmacist before using this medication.
As there is no sufficient experience on use of salmeterol and fluticasone during breastfeeding, use the medicine if your doctor decides that it is necessary.

It is not expected to create an impact on ability to drive and use machines.

Please inform your doctor if you are using Selective and nonselective beta blockers (heart medicine), ritonavir (a medicine used against the virus), ketoconazole (a medicine that acts against fungi) and drugs that inhibit P450 3A4 enzyme metabolism (such as ketoconazole), your doctor may wish to change your treatment.

- If you are currently using any prescription or non-prescription medication, or if you have used it recently, please inform your doctor or pharmacist about them.*

Instruction for proper use and dose/administration frequency:

In treatment of asthma:
Adults and adolescents over 12 years:
1 inhalation 2 times a day (pull the lungs with breath) (50 micrograms of salmeterol and 500 micrograms of fluticasone).

Chronic obstructive pulmonary disease (COPD):
Adults: 1 inhalation 2 times a day (pull the lungs with breath) (50 micrograms of salmeterol and 500 micrograms of fluticasone).

Use Roveflu by oral use in the form of inhalation.

When you breathe by inhaler the medication reaches your lungs. Therefore, it is important to take a deep breath in the device through the mouthpiece.

The use of the inhalation device will be shown to you by a doctor or other medical staff.

If Roveflu is prescribed to a child must be accompanied by an adult who understands the use.

The regular use of Roveflu is necessary to ensure the full benefits. Do not stop your treatment even if you feel better.
Do not change the dose of your medication without consulting your doctor.

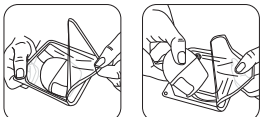
Do not swallow the capsules. The capsules must be used only with the inhaler (device) located inside the box. This device is designed for use with capsules containing specially Roveflu 50/500 mcg inhalation powder.

- Remove the foil pack just before you use the capsules. Never wash the mouthpiece or any part of the inhaler. Keep your hand, the capsule and the device always dry.
- After using your medicine Shake your mouth with water and spit the water in your mouth after shaking. It reduces the risk of development of mouth yeast infection (thrush):
- Do not use the capsule with any device other than the device in the box.
- Use Rovelli at the same time each day, it will help you remember when to use your medicine.
- Use Rovelli according to your doctor instructions, it is important that you use regularly.
- If you have any questions about how long to use Rovelli, consult your doctor or pharmacist.

Detailed information is available in the operating instructions for use.
For the correct use of the inhaler carefully follow the rules given below.

Instructions for use

Inhaler device is launched in the cardboard within the protective packaging for safety purposes.



 While using Roveflu, please do not forget to follow the instructions of your doctor carefully. The inhaler device is specifically designed for inhalation of Formoterol Neutec, inhalation capsule. It should not be used to take another drug.

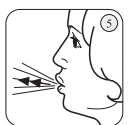
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1. Powder cap
 2. Mouthpiece
 3. Central reservoir
 4. Drill button
 5. Bottom reservoir

1. Open the powder cap completely by pulling it upward and then open the mouthpiece by pulling it upward.

2. Take a Roveflu inhalation capsule out of the blister strip (It is important that you take the capsule from the blister pack only immediately before you use it.) and as shown at figure 2, place it in the central reservoir. It does not matter direction of the capsule in the reservoir.

-  3. Close the mouthpiece tightly until it "clicks". Leave the powder cap open.

4. Keep the inhaler device upright and push the drilling button only a single motion and leave. Thus holes will be opened in the capsule and will allow the drug to be released when you breathe.

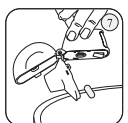


5. Breathe out fully.

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/hepatic impairment:

Formal pharmacokinetic studies using this medicine have not been conducted in patients with hepatic 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).

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:

- Slowedown 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:

neuro® Inhaler İlaç San. Tic. A.Ş.

Artıfiye / Sakarya/TURKEY