

Use in elderly:

Use in elderly is same as adults.

Special conditions:

Renal failure:

Formal pharmacokinetic studies have not been conducted in patients with renal impairment.

Liver failure:

Systemic bioavailability may increase in patients with hepatic impairment. Since the both budesonide and formoterol fumarate are predominantly cleared by hepatic metabolism, impairment of liver function may lead to accumulation of budesonide and formoterol fumarate in plasma. Therefore, patients with hepatic disease should be closely monitored.

It is recommended that the dose is gradually reduced when the treatment is discontinued. Treatment should not be stopped abruptly. Worsening or acutely deteriorating asthma is a life-threatening condition, it requires urgent medical control.

You should have their rescue inhaler available at all times, either **ROVEHALER Rovecort®** (for patients using **ROVEHALER Rovecort®** as maintenance and reliever therapy) or a separate rapid-acting bronchodilator (for patients using **ROVEHALER Rovecort®** as maintenance therapy only).

You should take the **ROVEHALER Rovecort®** maintenance dose as prescribed by your doctor, even when you do not have symptoms. Once asthma symptoms are controlled, your doctor may reduce your **ROVEHALER Rovecort®** dose gradually.

Your doctor will monitor you closely during the first 3 months of treatment. Serious asthma-related side effects and exacerbations may occur during treatment with **ROVEHALER Rovecort®**. You should continue treatment but seek medical advice if asthma symptoms remain uncontrolled or worsen after initiation of **ROVEHALER Rovecort®**.

The risk of pneumonia may increase in elderly patients who are combined with inhaled steroids. Clinical evidence for the advantage of high-dose use in COPD is insufficient.

*If you have the impression that the effect of **ROVEHALER Rovecort®** is either too strong or too weak, discuss this with your doctor or pharmacist.*

If you use more **ROVEHALER Rovecort® than you should**

*If you have used more **ROVEHALER Rovecort®** meg than you should, talk to your doctor or pharmacist immediately.*

The most common symptoms that may occur if you use more **ROVEHALER Rovecort®** meg than you should are trembling, headache or a rapid heartbeat.

If you forget to use **ROVEHALER Rovecort®**

If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose.

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

4. Possible side effects

Like all medicines, side effects may develop in patients which are sensitive to any ingredient of **ROVEHALER Rovecort®**.

Like all medicines, **ROVEHALER Rovecort®** can cause side effects, although not everybody gets them.

If either of the following happen to you, stop using **ROVEHALER Rovecort® and talk to your doctor IMMEDIATELY or go to the emergency department at your nearest hospital:**

- Swelling of your face, particularly around your mouth (tongue and/or throat and/or difficulty swallowing) or hives together with difficulty breathing (angioedema) and/or sudden feeling of faintness. This may mean that you are having an allergic reaction. This happens rarely, affecting less than 1 in 1,000 people.
- Sudden acute wheezing or shortness of breath immediately after using your inhaler. This happens very rarely, affecting less than 1 in 10,000 people.

These are very serious side effects. If you have any of these effects, you may need urgent medical attention.

Other possible side effects:

Side effects are listed in the following categories:

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

Rare: may affect up to 1 in 1,000 people

Very rare: may affect up to 1 in 10,000 people

Unknown: Cannot be estimated from the available data

Common (affects less than 1 in 10 people)

- Palpitations (awareness of your heart beating), trembling or shaking. If these effects occur, they are usually mild and usually disappear as you continue to use **ROVEHALER Rovecort®**.
- Thrush (a fungal infection) in the mouth. This is less likely if you rinse your mouth out with water after using your **ROVEHALER Rovecort®**.
- Mild sore throat, coughing and a hoarse voice
- Headache
- Tremor
- Pneumonia (infection in the lungs) in patients with COPD

Inform your doctor if you experience any of the following symptoms while using **ROVEHALER Rovecort®**. These symptoms may be signs of a lung infection:

- Fever or chills
- Increase in mucus production, change in mucus color
- Increased cough or increased difficulty breathing

Uncommon (affects less than 1 in 100 people)

- Feeling restless, nervous or agitated
- Disturbed sleep
- Feeling dizzy
- Nausea (feeling sick)
- Fast heart beat
- Bruising of the skin
- Muscle cramps
- Blurred vision

Rare (affects less than 1 in 1,000 people)

- Rash, itching
- Bronchospasm (tightening of the muscles in the airways which causes wheezing). If the wheezing comes on suddenly after using **ROVEHALER Rovecort®** stop using **ROVEHALER Rovecort®** and talk to your doctor immediately
- Low levels of potassium in your blood
- Uneven heart beat

Very rare (affects less than 1 in 10,000 people)

- Depression
- Changes in behaviour, especially in children
- Chest pain or tightness in the chest (angina pectoris)
- An increase in the amount of sugar (glucose) in your blood
- Taste changes, such as an unpleasant taste in the mouth
- Changes in your blood pressure
- An abnormal electrical signal in the heart (QTc interval prolongation)
- Cushing syndrome (an adrenal gland disease, that causes weight gain, round 'moon face', high blood pressure and excess hair development, due to high levels of cortisol in the blood
- Cataract (clouding of the lens in the eye)
- Glaucoma (increased pressure in the eye)

Inhaled corticosteroids can affect the normal production of steroid hormones in your body, particularly if you use high doses for a long time. The effects include:

- Changes in bone mineral density (thinning of the bones)
- Cataract (clouding of the lens in the eye)
- Glaucoma (increased pressure in the eye)
- A slowing of the rate of growth of children and adolescents
- An effect on the adrenal gland

These effects are much less likely to happen with inhaled corticosteroids than with corticosteroid tablets.

If any of the side effects get serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

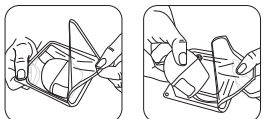
Inhaler instructions for use:

Inhaler is for you to inhale (inhale) the medicine in the **ROVEHALER Rovecort®** inhaler capsule that your doctor has prescribed for your respiratory problems.

Inhaler, which is presented to the market in a cardboard box, is placed in a protective packaging for safety purposes.

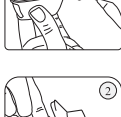


Please take out your device from the package before using as shown at figure.

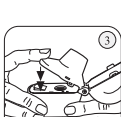


1. Powder cap
2. Mouthpiece
3. Central reservoir
4. Drill button
5. Bottom reservoir

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



2. Take a **ROVEHALER Rovecort®** inhaler capsule from the blister pack (it should be removed just before use) and place it in the central chamber as shown in the figure (2). It does not matter which direction the capsule is placed in the chamber.



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.

ROVEHALER Rovecort® 9/320 meg inhaler capsules contain a small amount of a powder, therefore, capsules are only partially filled.

5. How to store **ROVEHALER Rovecort®**

*Keep **ROVEHALER Rovecort®** and its package out of the reach and sight of children.*

Store at room temperature below 25°C. Store with the mouthpiece down.

Use it properly accordance to the expiry date

*Do not use **ROVEHALER Rovecort®** after the expiry date on the packaging.*

Do not use **ROVEHALER Rovecort®** if you notice defects in the product and / or packaging.

Manufacturer:
neutec Inhaler Ilac San. ve Tic. A.Ş.
Arifiye/ SAKARYA, TURKEY