

Rovetio[®] Capsair 18 mcg
capsule powder for inhalation

- **Active ingredient:** Each inhalation dose contains 22 mcg Tiotropium Bromide Anhydrous equivalent to 18 mcg Tiotropium.
- **Excipient:** Lactose

1. What ROVETIO is and what it is used for
2. Before you use ROVETIO
3. How to use ROVETIO
4. Possible side effects
5. How to store ROVETIO

You should not use this medicine unless specifically recommended by your doctor.

Like all medicines, this medicine can cause side effects, although not everybody gets them.

sudden reduction of your blood pressure or dizziness) may occur individually or as part of severe allergic reaction (anaphylactic reaction) after administration of ROVETIO. In addition, in common with all inhaled medicines, some patients may experience an unexpected tightness of the chest, coughing, wheezing or breathlessness immediately after inhalation (bronchospasm). If any of these occur, please consult your doctor immediately.

These are all very serious side effects. If one of these is present in you, then you have a serious allergy to ROVETIO. You may need to be admitted to an emergency medical intervention or hospital.
All of these very serious side effects are very rare.

The incidence rates of side effects are defined as follows:

Very common: more than 1 person in 10 people.
Common: can affect up to 1 person from 10 people.
Uncommon: can affect up to 1 person from 100 people.
Rare: can affect up to 1 person from 1000 people.
Very rare: can affect up to 1 person from 10000 people.
Unknown: It cannot be predicted by moving from the available data.

The following side effects have been reported in the patients taking this medication and are reported in terms of frequency:

Common:

- Dry mouth

Uncommon:

- Dizziness
- Headache
- Disorders of taste
- Blurred vision
- Heart rate irregularities (atrial fibrillation)
- Throat inflammation (pharyngitis)
- Aphonia
- Cough
- Reflux disease
- Constipation
- Mouth infections and throat fungal infections
- Rash
- Difficulty in making urine
- Painful urination

Rare:

- Difficulty in sleeping
- See halos or colored images around lights in relation to eye flushing (Glaucoma)
- High values in eye pressure measurements
- Irregular heartbeats (supraventricular tachycardia)
- Increase in heart rate (tachycardia)
- Feeling of heartbeats (palpitations)
- Coughing, wheezing or breathlessness (bronchospasm) with compression of the chest immediately after inhalation,
- Nose bleeding
- Inflammation of the throat (laryngitis)
- Inflammation of the sinuses (sinusitis)
- Obstruction of intestines or absence of bowel movements
- Inflammation of the gums
- Inflammation of the tongue
- Swallowing difficulty
- Inflammation in the mouth
- Nausea
- Hypersensitivity reactions, including sudden onset
- Serious allergic reaction leading to swelling of face or throat (angioedema)
- Rash
- Itching
- Urinary tract infection

Unknown:

- Discharge water from the body
- Tooth decay
- Severe allergic reaction (anaphylactic reaction)
- Infections or ulcers on skin
- Skin dehydration
- Swelling in joints

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

5. How to store ROVETIO

Keep ROVETIO out of the reach and sight of children and its package.
Store at room temperature below 25°C.

Use properly according to the expiry date.

Do not use ROVETIO after the expiry date.

The expiry date refers to the last day of that month.

If you realize any defect in its package and/or in the product, do not use ROVETIO

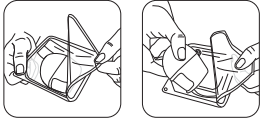
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Sakarya 1. Organize Sanayi Bölgesi 2. Yol No: 3
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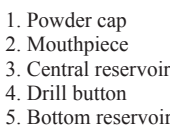
Instructions for correct use of inhalation device:
Inhaler device which is launched in the cardboard within the protective packaging for safety purposes.



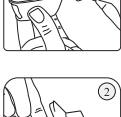
Please take out your device from the package before using as shown at figure.



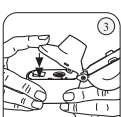
While using ROVETIO, please do not forget to follow the instructions of your doctor carefully. The inhaler device is specifically designed for inhalation of ROVETIO, inhalation capsule. It should not be used to take another drug.



1. Pulling the dust head up ensure that the mouthpiece is fully opened.



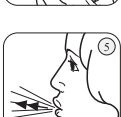
2. Take a ROVETIO inhalation capsule from blister package (It is important that you take the capsule from the blister pack only immediately before you use it.) and as shown at figure 2, place it in the central reservoir. It does not matter direction of the capsule in the reservoir.



3. Close the mouthpiece tightly until it clicks. Close as shown figure 3 to avoid pinching when you close the device. Leave the dust 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.



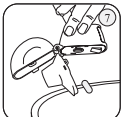
5. Breathe out fully.

Important: please never breathe into the mouthpiece.



6. Lift the inhalation device up to your mouth and close your lips tightly around the mouthpiece. Take a slow and deep breath by holding your head upright, adjust your breathing rate to hear or feel the capsule vibrating.

Inhale until your lungs are full, hold your breath for a period of time and remove the inhalation device from your mouth. Then breathe normally. Repeat steps 5 and 6 to empty capsule



7. Open the mouthpiece again. Turn the device and throw the used capsule. To clean dusts in the inside, use a dry soft tissue or a clean soft brush. Close the mouthpiece and dust cap and leave your device.

NOTE: DO NOT USE WATER to clean the inhaler device. The capsules should not be exposed to extreme temperatures. ROVETIO inhaler capsules contain a small amount of dust, so capsules are only partially filled.

Questions and answers about the application

1. How do I prevent the capsules from breaking into small particles?

During device use, the capsules may break and small particles may escape into your mouth or throat while breathing. You can prevent this by applying the following:

- Holding the capsules in their original packaging (blister packages) before use.
- By storing the capsules at room temperature below 25°C.
- Protect the capsules from moisture.

2. Are capsule particles harmful?

No. The capsule is made of non-harmful edible gelatin. The gelatin particles that slip down to your mouth or throat can be swallowed.

3. How do I remove the capsule stuck in the capsule compartment?

Open the device, turn it upside down, and gently tap the bottom.

4. How do I know if I really took the dose?

- When you breathe through the device, you will detect that the capsule vibrates.
- You will feel the 'sugar taste' from lactose in your mouth. You may feel dust in the back of your throat. This is normal.
- When the dose is taken, the capsule will be empty.

5. How do I clean the dust inside the device?

- Use a dry tissue or a soft brush.
- Keep in mind that you should never wash the device.