

PACKAGE LEAFLET: INFORMATION FOR USER

RESPITEC 20/100 mcg Inhalation Aerosol

Used by inhalation.

- **Active substance:** Each inhalation dose contains 21 microgram ipratropium bromide monohydrate equivalent to 20 microgram ipratropium bromide and 120.0 microgram salbutamol sulfate equivalent to 100 microgram salbutamol.
- **Excipient (s):** HFA134A

**Read all of this PACKAGE LEAFLET carefully before you start taking this medicine because it contains important information for you.**

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *Inform your doctor that you are using this medicine, when you go to a hospital or see a doctor while using this medicine.*
- *Comport all information in this leaflet. Do not use **high** or **low** dose besides the dose recommended for you.*

**What is in this leaflet?**

1. **What RESPITEC is and what it is used for?**
2. **Before you take RESPITEC?**
3. **How to take RESPITEC?**
4. **Possible side effects**
5. **How to store RESPITEC?**

**Titles are included.**

**1. What RESPITEC is and what it is used for?**

- RESPITEC Inhalation Aerosol is a pressurized suspension prepared for use by mouth (by inhalation). When it is sprayed, it forms aerosols and reaches the lungs in this way. It is applied with a tool called an inhaler.
- RESPITEC 20/100 mcg Inhalation Aerosol is presented to the market in aluminum tubes with corresponding suspension of 200 metered doses.
- Ipratropium bromide, one of the active ingredients of RESPITEC, belongs to a drug group called anticholinergics. The other active ingredient, salbutamol, belongs to a group of drugs called beta-adrenergics. Both drug groups are members of a broader class of drugs called bronchodilators (bronchodilators). Bronchodilators (bronchodilators) are drugs that expand the airways in your lungs to make it easier for the air to get in and out of your lungs and to help you breathe.

Ipratropium bromide and salbutamol show the expanding effects of airways through different mechanisms. By using these two substances together as a combination, a greater bronchodilatory effect is achieved than with the use of each ingredient alone.

- RESPITEC helps in the breathing of more people with obstructive airways disease (Chronic Obstructive Pulmonary Disease-COPD) and more than one bronchial opener. COPD is a long-acting pulmonary disease that causes breathlessness and coughing. COPD is used to mean a table associated with the disease, chronic bronchitis and emphysema.

RESPITEC, when administered by inhalation, has a selective effect on the lungs locally. The enlargement seen in the bronchi after RESPITEC left is mainly an area-specific effect (airways), not an effect on the whole body (systemic).

For a successful treatment, the metered dose aerosol device should be used correctly. Please refer to "3. How to use RESPITEC?" and" Instructions for use of the inhalation spray ".

**2. What you need to know before you take RESPITEC**  
**DO NOT use RESPITEC:**

- If;
- You are hypersensitive (allergic) to ipratropium bromide, salbutamol or any other excipients in this drug,
  - You are hypersensitive (allergic) to atropine or its derivatives,
  - If your doctor tells you that you have a heart disease called hypertrophic obstructive cardiomyopathy,
  - Your doctor tells you that you have a heart disease called tachyarrhythmia.

**TAKE SPECIAL CARE with RESPITEC in the conditions listed below:**

- Sudden hypersensitivity reactions may occur after administration of RESPITEC; in this way, rare cases of hives, mouth, tongue and throat swelling (angioedema), rashes and wheezing were seen.
- Unintentional exposure to the eye may result in enlargement of the eyeball, eye pain or blurred vision, and increased intraocular pressure.
- Feeling pain or discomfort in the eye with blushing, blurred vision, seeing halting or colored images, sudden glaucoma (increase in intraocular pressure / eye pressure) may be indicated. If these statements occur in any combination, the opinion of an expert physician must be obtained immediately.
- Make sure your doctor or pharmacist knows how to use RESPITEC correctly. You should be careful not to contact the aerosol in the RESPITEC with your eyes. If your intraocular pressure is high (glaucoma) or if there is a tendency (risk) in your eyes, it is more important to protect your eyes.
- You may not have enough uncontrolled diabetes (diabetes), recent heart attacks (myocardial infarction), severe heart or vascular diseases, hyperthyroidism of the thyroid gland (hyperthyroidism), special tumor in the adrenal glands (pheochromocytoma) if you have conditions that make it difficult to urinate, such as a risk or prostate enlargement or blockage in the bladder neck, you should tell your doctor.
- If you have severe cardiac disease, consult your doctor if you notice any symptoms of chest pain or other symptoms when using your medicine.
- Tell your doctor if you are taking other medicines to help you breathe. This group of drugs can cause a decrease in the amount of potassium in your blood.
- If you have a rare hereditary disease called cystic fibrosis, you may be more prone to gastrointestinal problems.
- In case of a rapidly worsening breathing difficulty, contact your doctor immediately.
- Contact your doctor if you need higher doses of ipratropium bromide / salbutamol sulfate to relieve symptoms of your illness.
- RESPITEC may prevent contractions of the uterus at birth. If you are pregnant during the last three months of pregnancy, consult your doctor.
- If a urine sample is required for a doping test within the tests performed on athletes, tell them that you are using RESPITEC to the test taker; because salbutamol in your medicine can lead to a positive test result.
- If you begin to wheeze after breathing RESPITEC or if another respiratory failure occurs (bronchial contraction due to inhalation), do not take any more doses and contact your doctor immediately.
- Your doctor will decide for the duration of the treatment with RESPITEC and this time will depend on the condition of your illness.

RESPITEC is for inhalation use only. You do not drink this medicine or use it by injection.

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

**Using RESPITEC with food and drink**

RESPITEC is not affected by food and drink because it is administered by inhalation.

**Pregnancy**

*Consult your doctor or pharmacist before using this medication.*

RESPITEC during pregnancy only, your doctor careful risk-benefit assessment then you should use it if you think it is necessary.

During the treatment you can use a contraceptive method which is considered to be medically effective.

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

**Breast-feeding**

*Consult your doctor or pharmacist before using this medication.*

You should only use RESPITEC during breastfeeding if it is deemed necessary by your doctor after a careful risk-benefit assessment.

RESPITEC goes to the top; but the effects on the newborn are unknown.

**Driving and using machines**

The effects on the ability to drive cars and machines have not been studied.

However, during RESPITEC treatment, adverse effects such as dizziness, eye disturbance at different distances, enlargement of eye babies and blurred vision may occur. For this reason, it is necessary to be careful when driving a car or operating a machine. If any of the above-mentioned side effects occur, you should stay away from potentially hazardous work such as driving or operating a machine.

**Other medicines and RESPITEC**

If you are using any of the following medications together, be more careful and you need to tell your doctor that you are taking these medicines:

- Xanthine derivatives (such as theophylline), other beta-adrenergics (some are respiratory drugs) and anticholinergics (these are medicines used in constipation, Parkinson's disease, frequent urination and incontinence)
- Corticosteroid group drugs (cortisone, used in situations where the immune system should be suppressed),
- Diuretics (diuretics),
- The heart medicine, called digoxin,
- Beta-blockers (cardiovascular drugs),
- Monoamine oxidase (MAO) inhibitors or tricyclic antidepressants used in the treatment of psychological breakdown (depression)
- Some anesthetic gases. These medicines are used for the narcotics of the patient during surgery.
- If you have an operation, tell your doctor that you are using RESPITEC.

*Please inform your doctor or pharmacist if you are using or have recently used any medicine with or without a prescription.*

**3. How to use RESPITEC?**

**Instructions for proper use and dose / administration frequency:**

Follow your doctor's instructions as to when and how you will use your medicine and always read the instruction manual. If you are unsure, check

**Adults / Elderly/ Children older than 12**

The usual recommended dose is two injections four times daily.

This dose can be increased up to a maximum of 12 sprays within 24 hours, depending on the need.

**Route and method of administration:**

The correct use of the inhalation spray will be shown to you by the doctor or pharmacist.

Your doctor should occasionally check how you use the inhalation spray.

To control your disease, you should use your RESPITEC inhalation spray regularly and as prescribed by you.

The medication is placed in a pressurized tube within the plastic body, including mouthpiece.

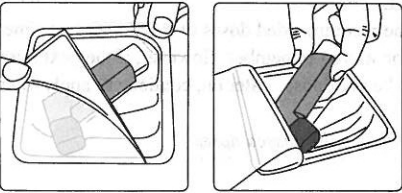
For proper use of the inhalation spray, follow carefully the following instructions.

**Instruction for use of inhalation spray**

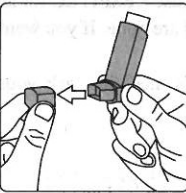
The aerosol for inhalation, which is presented to the market in a cardboard box, is contained in a protective packaging for safety purposes.



Before using the aerosol for inhalation, remove it from its packaging as shown in the figure.



**Testing the inhalation spray:**

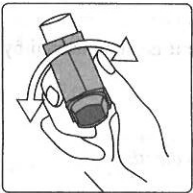


Test if your inhalation spray will work the first time you use it. Remove the mouthpiece cover by gently squeezing it with your thumb and fingers from the sides and pull it apart.

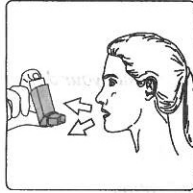
To make sure it works, shake your inhaler spray, keep the mouth away from yourself, and press the tube to release a puff of air. If you have not used your inhalation spray for a week or longer, you should remove the mouthpiece cover and two times puff to the gap.

When you will use your inhalation spray, stand upright on your seat or standing.

1. Remove the mouthpiece cover as shown in the first picture. Check inside and outside to make sure the mouthpiece is clean.
2. Thoroughly shake your inhalation spray before each use.



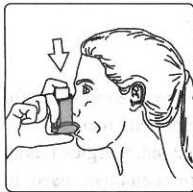
3. Keep your inhalation spray perpendicular to the bottom of your inhaler spray, below the mouth of your thumb.



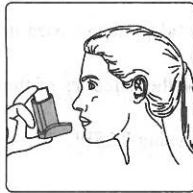
4. Put your mouthpiece between your teeth and tightly close your lips.



5. Slowly and deeply breathe in your mouth and press on the top of your inhalation spray to dispense a puff dose at the same time.



6. Hold your breath for about 10 seconds or as easily as you can, and remove the mouthpiece from your mouth and pull your fingertip from the top of your inhalation spray. Then slowly breathe in orally. You avoid breathing into the inhaler.



7. Wait for about half minute between each puff of medication and then repeat the steps 2-6.

8. After use, close the cover of the mouthpiece immediately to protect it from dust. When the mouthpiece cover is correctly positioned, it will fit in place. If not, turn the mouthpiece cover in the other direction. Do not apply too much force.

If you see "steam" from the top of the spray or from the sides of your mouth, you should restart the application from step 2. There is pressure within the aerosol tube. For this reason, it should not be opened by force at all and should not be exposed to temperatures above 50 °C. Since the aerosol tube is not transparent, it is not possible to see whether the contents are finished; but the shaking of the tube will indicate that no liquid remains inside.

The mouthpiece should always be kept clean. Can be washed with warm water. If soap or detergent is used, the mouthpiece must be thoroughly rinsed with water. The mouthpiece must be thoroughly dried before use.

#### Different age groups:

**Usage in Children:** The use of RESPITEC in children is not recommended because of the lack of information in children.

**Usage in Elderly:** Elderly patients can use RESPITEC without a special dose adjustment.

#### Special usage conditions:

**Renal / Hepatic impairment:** Since RESPITEC is not examined in patients with liver or kidney failure, it should be used with caution in such patients.

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

#### If you use more RESPITEC than you should:

*If you have used more RESPITEC than you should, talk to a doctor or pharmacist.*

#### If you forget to use RESPITEC:

If you forget to take one of the recommended doses of RESPITEC on time, do not worry and apply as soon as you remember. However, if the next dose is nearing its time, wait and take your dose. Later on, continue to apply your medicine as before.

*Do not take double doses to balance the missed doses.*

#### If you stop taking RESPITEC:

The termination of RESPITEC treatment before it is necessary may lead to a worsening of your disease. For this reason, continue to use RESPITEC for as long as your doctor prescribes, even if your complaints are gone. If you want to stop this treatment, you should consult your doctor.

If you have any other questions about the use of this medicine, ask your doctor or pharmacist.

#### 4. Possible side effects?

Like all medicines, RESPITEC can cause side effects in individuals who are hypersensitive to any substance in the content of them.

**If any of the following occurs, stop using RESPITEC and tell your doctor IMMEDIATELY and contact the emergency department of your nearest hospital:**

- The combination of salbutamol sulfate / ipratropium bromide has been reported to cause hypersensitivity reactions such as skin rashes, tongue, lips and face swelling (angioedema), rashes, blockage of the trachea, and the reactions are repeated with some reopening. In the majority of these patients, there was an allergy history against other medicines and / or foods, including soybean meal.

These are all very serious side effects.

If such effects are present in you, then you have a serious allergy against RESPITEC. You may need to be admitted to an emergency medical intervention or hospital.

All of these very serious side effects are very rare.

**If you notice any of the following, tell your doctor immediately or contact the emergency department of your nearest hospital:**

- The presence of other problems when breathing or breathing,
- Pain or blurred vision in the eye as a result of unintentional exposure to the eye, increased intraocular pressure. There may be a feeling of pain or discomfort in the eye with blushing, blurred vision, seeing halos or colored images, or glaucoma suddenness. If these statements occur in any combination, the opinion of an expert physician must be obtained immediately.
- Changes in blood pressure and heart rhythm; the heart is too fast and light to throw, the heart muscle is not enough blood to go,
- Swelling in the mouth (edema), spasm in the bronchi immediately after inhalation

All these are serious side effects. Immediate medical attention may be required.

Serious side effects are very rare.

#### Tell your doctor if you notice any of the following:

Salbutamol sulfate/ipratropium bromide combination also caused the following undesirable effects:

“Uncommon” adverse effects (less than 1 in 100 people, more than 1 in 1.000 people):

- Irritability,
- Dizziness, headache, chills,
- Palsy, rapid heart rate,
- Cough, disturbances of the stomach, irritation of the throat,
- Mouth buildup, nausea,
- Skin reactions,
- Elevation in large (systolic) blood pressure.

“Rare” adverse effects (less than 1 in 1.000 people, more than 1 in 10.000 people):

- Decrease in potassium levels in your blood,
- Mental disorder,
- Disappearance of the eyes in accordance with different distances, accumulation of fluid in the corneal layer of the eye (edema), redness in the conjunctiva layer of the eye, sighting of haloes, pupil growth,
- Bronchial spasms, throat constipation, larynx spasms,
- Gastro-intestinal movement disorders, diarrhea, constipation, vomiting, inflammation in the mouth,
- Excessive sweating, rash, itching
- Muscle spasms, muscle weakness, muscle pain,
- Difficulty in urinating,
- General malaise (asthenia),
- Small (diastolic) blood pressure drop.

These are mild side effects of the ipratropium bromide / salbutamol sulfate combination.

*If you encounter any side effects not mentioned in these instructions for use, please inform your doctor or pharmacist.*

#### 5. How to store RESPITEC?

*Store RESPITEC in places where it cannot be seen, cannot be accessed by children and in its packaging.*

Store RESPITEC at room temperature below 25°C. Protect directly from sunlight and freezing. The aerosol box should not be drilled, even if it is empty, it should not be broken and kept away from fire.

#### Use in accordance with the expiration date.

*Do not use RESPITEC after the expiration date on the packaging.*

The expiration date is the last day of the specified month.

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

#### Marketing Authorisation Holder & Manufacturer:

**neutec** Inhaler İlaç San. ve Tic. A.Ş.

Arifiye / SAKARYA / TURKEY

Phone : +90 850 201 23 23

Fax : +90 212 481 61 11

e-mail : info@neutecinhaler.com