

## PATIENT LEAFLET: INFORMATION FOR THE USER

### RESPITEC 0.5 mg / 2.5 mL + 2.5 mg / 2.5 mL inhalation solution for nebulization

#### For oral or nasal use by inhalation.

- **Active ingredient:** Each 2.5 mL flacon contains 0.52 mg ipratropium bromide monohydrate equivalent to 0.5 mg ipratropium bromide and 3.01 mg salbutamol sulfate equivalent to 2.5 mg salbutamol.
- **Excipients:** Purified water, sodium chloride, hydrochloric acid.

#### Read all of this 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 only you. Do not pass it on to others.*
- *During the use of this medicine, inform your doctor that you are using this medicine when you go to the doctor or hospital.*
- *Adhere strictly instructions in this leaflet. Do not use **high** or **low** doses other than the recommended dose.*

#### What is in this leaflet:

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

#### 1. What RESPITEC is and what it is used for

The name of your medicine is RESPITEC. You use it with a device called a nebuliser. This changes your medicine into a mist for you to breathe in. RESPITEC contains two different medicines called:

- Ipratropium bromide
- Salbutamol sulfate

Both belong to a group of medicines called "bronchodilators". They are used to make breathing easier in an illness called "chronic obstructive pulmonary disease" or COPD. They work by opening up your airways. RESPITEC is presented as 20 pieces in a single-use translucent low density polyethylene 2.5 mL flacon wrapped in aluminum foil in a box.

#### 2. What you need to know before you take RESPITEC?

##### Do not use RESPITEC

If,

- You are allergic (hypersensitive) to ipratropium or salbutamol or any of the other ingredients in RESPITEC
- You are allergic to similar medicines which contain atropine or medicines like atropine
- You have a heart problem called "hypertrophic obstructive cardiomyopathy". This is where the wall between the two sides of the heart gets bigger and blocks the blood flow
- You have a very fast heart beat (called "tachyarrhythmia")
- You are pregnant, likely to get pregnant or are breast-feeding

Do not use if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using RESPITEC.

##### Take special care with RESPITEC

Check with your doctor or pharmacist before using this medicine if:

- You have glaucoma, or have been told that you may develop it
- You have heart or circulation problems, or have had a recent heart attack
- You have diabetes
- You have an over-active thyroid gland
- You have problems passing water (urine)
- You are a man who has prostate problems
- You have cystic fibrosis
- You have ever had something called 'pheochromocytoma'. This is a rare tumour which is not malignant. Using your inhaler can make the symptoms of this worse
- A condition known as "lactic acidosis" has been reported in association with high therapeutic doses of salbutamol, mainly in patients being treated for an acute bronchospasm (see Section 3 and 4). Increase in lactate levels may lead to shortness of breath and hyperventilation even though there may be improvement in your wheezing. If you feel that your medicine is not working as well as usual and you need to use the nebuliser more than your doctor has recommended, immediately talk to a doctor.

If you are not sure if any of these apply to you, talk to your doctor or pharmacist before using RESPITEC.

Please consult your doctor if these warnings are valid for you, even at any time in the past.

##### RESPITEC with food and drink

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

##### Pregnancy

Consult your doctor or pharmacist before taking this medicine.

Do not use RESPITEC if you are pregnant, likely to get pregnant.

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

##### Lactation

Consult your doctor or pharmacist before taking this medicine.

RESPITEC should not be used during lactation.

##### Driving and using machines

You may feel dizzy, or have difficulty in focusing, or blurred vision whilst taking RESPITEC. If this happens do not drive or use tools or machines.

#### Important information about some of the ingredients of RESPITEC

There is no excipients in the content of RESPITEC that requires special warning.

#### Other medicines and RESPITEC:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because RESPITEC can affect the way some other medicines work. Also some other medicines can affect the way RESPITEC works.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Steroid medicines such as prednisolone
- Water tablets (also called diuretics)
- Medicines for depression
- Medicines to help your breathing
- Medicines called "anti-cholinergics". These can be used to treat colic pain, Parkinson's Disease, problems passing water or lack of control of your bladder or bowels
- Medicines called "beta blockers" such as propranolol. These can be used to treat heart problems, high blood pressure, anxiety or migraine
- Medicines called "beta mimetics" such as fenoterol for breathing problems
- Digoxin - used for a fast heart beat or heart failure

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using RESPITEC.

#### Operations

Some gases used in operations (anaesthetic gases) may affect how your medicine works. If you are about to have surgery, make sure you mention that you are taking RESPITEC to the doctor, dentist or anaesthetist.

#### Tests

If you have to provide an urine sample as part of a routine sport drug test, tell the person giving the test that you are taking this medicine. This is because RESPITEC contains salbutamol and this may lead to a positive result.

*Inform your doctor or pharmacist if you are using or have recently used any prescription or non-prescription medication medicines.*

#### 3. How to use RESPITEC

##### Instructions for proper use and dose/frequency of administration:

Always use your medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Follow these instructions to get the best results. If anything is unclear after reading this leaflet, ask your doctor, pharmacist or practice nurse.

##### Dose:

The usual dose is the contents of 1 single dose unit, three or four times a day for: Adults (including the elderly) and children over 12 years.

RESPITEC is not recommended for children under 12 years.

Do not swallow or give this medicine by injection.

Do not use more than your doctor has told you

See your doctor straight away if:

- You feel that your medicine is not working as well as usual
- You need to use the nebuliser more than your doctor has recommended

Your doctor may need to check how well your medicine is working.

In some cases your doctor may need to change your medicine.

##### Method of administration:

RESPITEC Inhalation Solution can be administered with a suitable nebulizer or intermittent positive pressure respirator (ventilator). For the correct use of RESPITEC, see the application instructions at the end of this leaflet. If you are still not sure, consult your doctor or pharmacist.

##### Different age groups:

###### Use in children:

Due to lack of information in children, RESPITEC is not recommended for use in children under 12 years of age. Due to insufficient information in children, RESPITEC is not indicated under 12 years of age.

###### Use in elderly:

Elderly patients can use RESPITEC without a special dose adjustment.

##### Special cases:

###### Renal / Liver failure:

Since RESPITEC has not been studied in patients with hepatic or renal insufficiency, it should be used with caution in such patients.

*Please ask your doctor if you think that the effect of RESPITEC is too strong or too weak.*

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

*If you use more of RESPITEC than you should, talk to a doctor.*

If you use RESPITEC more than the recommended dose, depending on the ipratropium bromide it contains, some effects such as dry mouth and eye adjustment disorders may occur in a short time. These effects are mild and temporary. Because absorption in the body is low after inhalation or oral administration.

Symptoms of overdose with salbutamol, the other active ingredient in the formula of this medicine, include: increased heart rate (tachycardia), palpitations, tremors, increased blood pressure, low blood potassium level, low blood pressure, widening of pulse pressure, changes in heart rate, anginal pain and flushing. A medical condition called metabolic acidosis has also been reported with excessive intake of salbutamol.

In case of salbutamol overdose, your doctor will apply the necessary treatment to you. However, if you have a history of bronchospasm (contraction of the bronchi), your doctor will decide considering this situation.

#### **If you forget to take RESPITEC**

If you forget a dose, take it as soon as you remember it. However, if it is time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you have any further questions, ask your doctor or pharmacist.

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

#### **If you stop using RESPITEC:**

Terminating RESPITEC treatment prematurely may cause your disease to worsen. Therefore, even if your complaints have disappeared, continue to use RESPITEC as long as your doctor prescribes. If you want to stop this treatment, consult your doctor.

If you have any further questions, ask your doctor or pharmacist.

#### **4. Possible side effects**

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

**If you experience any of the following serious side effects or symptoms, stop taking RESPITEC and tell your doctor immediately or go to the nearest hospital emergency department:**

- If after taking RESPITEC you are wheezy or have other difficulties in breathing, do not take any more (unless you have been told to by your doctor)
- Allergic reactions - the signs may include skin rash, itching and nettle rash. In severe cases the signs include swelling of your tongue, lips and face, sudden difficulties in breathing and a fall in your blood pressure that may cause dizziness.

See your doctor straight away if you have any of these side effects.

These are all very serious side effects.

If you have one of these, you have a serious allergy to RESPITEC. You may need immediate medical care or hospitalization.

**Tell your doctor if you experience any of the following:**

The side effects described below have been experienced by people taking RESPITEC.

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, more than 1 in 100 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

#### **Uncommon**

- Feeling nervous, shaky or dizzy
- Dry mouth
- Cough, headache
- Feeling sick (nausea)
- Throat irritation
- Increase in blood pressure
- Increased heart rate or uneven heart beats (palpitations)
- Voice problems (dysphonia)
- Skin reactions

#### **Rare**

- Anaphylactic reaction, hypersensitivity, angioedema (tongue, lips and face swelling)
- Irregular heart beat
- Regular but abnormally fast heart rate (supraventricular tachycardia)
- Chest pain (due to heart problems such as angina). Tell your doctor or pharmacist if this occurs but do not stop taking this medicine unless told to do so
- Blurred vision, dilated pupils, glaucoma, painful, stinging, or red eyes, swelling of the eyes, see colours or lights
- Increased sweating
- Unexpected tightening of the chest immediately after inhaling the medicine
- Dry throat, swelling of the throat
- Difficulty in breathing or speaking due to a brief spasm of your vocal muscles
- Diarrhoea, constipation, being sick (vomiting) or other problems with your digestive system
- Inflammation of the mouth
- Muscle cramps, muscle weakness and pain
- Difficulty in passing water (urine)
- Feeling weak
- Fall in blood pressure
- Mood changes
- Mental disorder (dysfunction of the brain that may occur with a disease or other secondary factors)

You may also get unusually low levels of potassium in your blood (called hypokalemia). If this happens, your doctor will keep checking your potassium levels.

#### **Unknown**

The condition known as lactic acidosis can cause abdominal pain, hyperventilation, and shortness of breath (even with an improvement in wheezing), hand-foot cold, irregular heart rhythm, or thirst.

If any of these side effects make you uncomfortable or aggravated, or if you experience any side effects not included in this leaflet, consult your doctor or pharmacist.

If any of the liquid or mist accidentally gets into your eyes you may get painful, stinging or red eyes, dilated pupils, blurred vision, see colours or lights. If this happens, talk to your doctor for advice. If you get problems with your eyes at any other time, talk to your doctor for advice.

*If you experience any side effects not mentioned in this leaflet, inform your doctor or pharmacist.*

#### **5. How to store RESPITEC?**

Keep RESPITEC out of the sight and reach of children.

Store room temperature below 25 °C in dry place. Keep away from direct sunlight.

Do not use if the medicine is discoloured.

#### **Use in accordance with the expiry date.**

Do not use RESPITEC after the expiry date which is stated on the package.

If you notice any defects in the product and/or packaging, do not use RESPITEC.

#### **Marketing Authorisation Holder and Manufacturer:**

**neutec** İnhaler İlaç San. Tic. A.Ş.

Arifiye / Sakarya / TURKEY

#### **Instructions for use**

Single-dose flacons are for inhalation use only with appropriate nebulizer devices and must not be taken orally or administered parenterally.

1. Get your nebuliser ready by following the manufacturer's instructions.
2. Take a single-dose flacon from the strip.

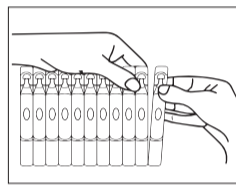


Figure 1

3. Hold the single dose flacon upright and open it by twisting off the top.

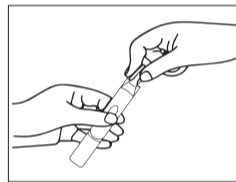


Figure 2

4. Squeeze all the contents of the flacon into the nebuliser chamber.

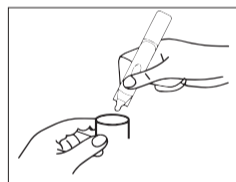


Figure 3

5. Assemble the nebulizer parts and use as directed by your doctor.

6. After you have finished, dispose of any leftover medicine carefully and follow the manufacturer's instructions on how to clean your nebuliser.

Since single-dose flacons do not contain preservatives, it is important to use the flacon immediately after opening and to open a new flacon at each application in order to prevent contamination with microbes. Single-dose flacons that have been partially used, opened or damaged should not be used.

You should be careful not to mix RESPITEC with other medicines in the same nebulizer.