

## Package leaflet: Information for the user

### Ipratropium bromide/salbutamol Neutec 0.5 mg/2.5 mg per 2.5 ml nebuliser solution

ipratropium bromide/salbutamol

**Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Ipratropium bromide/salbutamol Neutec is and what it is used for
2. What you need to know before you use Ipratropium bromide/salbutamol Neutec
3. How to use Ipratropium bromide/salbutamol Neutec
4. Possible side effects
5. How to store Ipratropium bromide/salbutamol Neutec
6. Contents of the pack and other information

#### **1. What Ipratropium bromide/salbutamol Neutec is and what it is used for**

Ipratropium bromide/salbutamol Neutec contains the active substances ipratropium bromide and salbutamol. Both belong to a group of medicines called bronchodilators, which help to improve your breathing by opening up your airways. This is achieved by preventing the contraction of the smooth muscles surrounding the airways, therefore allowing the airways to remain open.

Ipratropium bromide/salbutamol Neutec is used in adults, and adolescents aged 12 years and above to treat long-term breathing problems in an illness called 'chronic obstructive pulmonary disease' or COPD.

#### **2. What you need to know before you use Ipratropium bromide/salbutamol Neutec**

##### **Do not use Ipratropium bromide/salbutamol Neutec, if you:**

- are allergic to salbutamol, ipratropium bromide, atropine (including medicines similar to atropine) or any of the other ingredients of this medicine (listed in section 6).
- have a heart problem called 'hypertrophic obstructive cardiomyopathy'. This is a disease in which the wall between the two sides of the heart becomes thickened. The thickened wall can make it harder for the heart to pump blood and may block the blood flow.
- have a very fast heart beat (called 'tachyarrhythmia').

##### **Warnings and precautions**

Talk to your doctor or pharmacist before using Ipratropium bromide/salbutamol Neutec, if you:

- have glaucoma (increased pressure in the eyes), or have been told that you may develop it. Your doctor will advise you to protect your eyes when using this medicine.
- have heart or circulation problems (e.g. get pain in the legs when walking), or have had a recent heart attack.
- have diabetes.
- have an over-active thyroid gland.
- have problems passing water (urine).
- are a man who has prostate problems.
- have cystic fibrosis.

- have an intestinal obstruction.
- have a tumour of the adrenal gland (called ‘pheochromocytoma’) which is not malignant. Using this medicine can make the symptoms of this worse.
- have impaired liver- or kidney function.

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 sections 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.

Consult a doctor or go to your nearest hospital immediately in case of sudden worsening of your breathing difficulties or when the prescribed dose does not give you as much relief in breathing as before. Do not increase the dose without the doctor’s advice.

Good oral hygiene and regular dental check-ups are recommended since Ipratropium bromide/salbutamol Neutec may cause dry mouth which increases the risk of tooth decay.

It is very important to avoid getting the medicine in your eyes, in particular if you have or have a risk of developing glaucoma. If any of the liquid or mist accidentally gets into your eyes you may get eye problems such as painful, stinging or red eyes, enlarged pupils, blurred vision, see colours or lights. If this happens, talk to your doctor immediately for advice. If you get problems with your eyes at any other time, talk to your doctor for advice.

Use of Ipratropium bromide/salbutamol Neutec can sometimes cause lowering of potassium levels in the blood, particularly if you are taking certain other medicines at the same time. If you are at risk of this happening, your doctor might monitor the amount of potassium in your blood.

If you have to provide a urine sample as part of a routine drug test, Ipratropium bromide/salbutamol Neutec may give a positive test result.

### **Children**

This medicine is not recommended in children below 12 years of age because it has not been studied in this age group.

### **Other medicines and Ipratropium bromide/salbutamol Neutec**

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

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

- Steroid medicines such as prednisolone used in treatment of inflammatory diseases, which may increase the effect of this medicine and the severity of side effects.
- Water tablets (also called ‘diuretics’).
- Certain medicines to treat depression and anxiety (“anti-depressants”). This class of medicines includes monoamine oxidase inhibitors (e.g. Phenelzine) or tricyclic antidepressants (e.g. Amitriptyline), that may increase the effect of salbutamol.
- Other medicines to help your breathing, including inhalers and tablets for asthma and medicines for treatment of an acute asthma attack. These medicines include beta-agonists (e.g. fenoterol), xanthine derivatives (e.g. theophylline or aminophylline), and anticholinergics (e.g. tiotropium), that may increase the effect of this medicine and the severity of side effects.
- Medicines called ‘anticholinergics’. 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. Taking beta-blockers may inhibit the effects of Ipratropium bromide/salbutamol Neutec.

- Digoxin – used for a fast heart beat or heart failure, which can result in heart rhythm disorders when used together with this medicine.

### **Operations**

Some gases used in operations (anaesthetic gases) may increase the sensitivity to side effects on the heart by salbutamol. If you are going to have surgery, you will be monitored carefully or your doctor may decide to stop the use of Ipratropium bromide/salbutamol Neutec. If you are about to have surgery, make sure you mention that you are taking Ipratropium bromide/salbutamol Neutec to the doctor, dentist or anaesthetist.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Do not use Ipratropium bromide/salbutamol Neutec if you are pregnant, unless your doctor decides that the benefit to you outweighs any risk to your child.

If you are breast-feeding the doctor will decide if you should discontinue breast-feeding or discontinue/abstain from this medicine, taking into account the benefit of breast-feeding for the child and the benefit of treatment for you.

### **Driving and using machines**

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

## **3. How to use Ipratropium bromide/salbutamol Neutec**

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

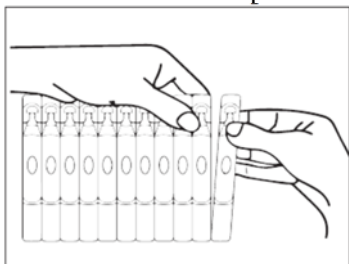
The recommended dose for **adults and adolescents over 12 years of age** is:  
the contents of 1 single-dose container, three or four times a day.

Ipratropium bromide/salbutamol Neutec should be inhaled using a suitable nebuliser, e.g. jet nebuliser. Please read the full instructions for use of the nebuliser in the leaflet provided with the nebuliser before starting the inhalation.

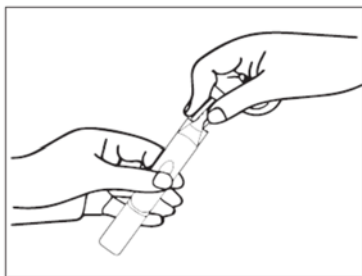
### **Instructions for use**

Read through numbers 1 to 5 first, before starting to use your nebuliser.

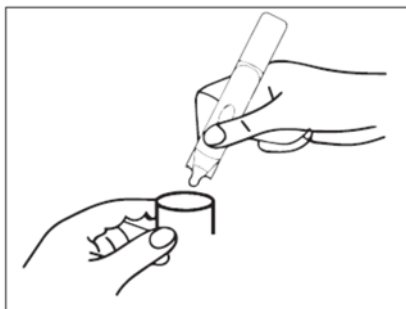
1. Prepare your nebuliser for use according to the manufacturer's instructions and advice from your doctor.
2. Open the pouch and carefully separate a new container from the strip. Never use an ampoule that has been opened already or if the nebuliser solution is discoloured.



3. Hold the ampoule upright and twist off the top.



4. Squeeze the entire contents into the nebuliser chamber, unless the doctor has given other instructions. Ensure all of the content is used immediately. Any unused medicine must be discarded and not used.



5. Start and use the nebuliser according to the instructions for use. Inhale with calm, even breaths through the mouthpiece/nebuliser mask.

#### **If you use more Ipratropium bromide/salbutamol Neutec than you should**

If you use more of this medicine than you should, you may experience symptoms such as: dry mouth, blurred vision, rapid heartbeat, chest pain, high blood pressure, irregular heartbeat, shaking, low blood pressure, and reddening of the skin. If you use more of this medicine than you should, you should talk to a doctor or go to your nearest hospital straight away.

#### **If you forget to use Ipratropium bromide/salbutamol Neutec**

- If you forget a dose, take it as soon as you remember it.
- Do not take a double dose to make up for a forgotten dose.

#### **If you stop using Ipratropium bromide/salbutamol Neutec**

Do not stop using Ipratropium bromide/salbutamol Neutec without first talking to your doctor.

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

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

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

**Stop using Ipratropium bromide/salbutamol Neutec and contact a doctor or go to the nearest emergency department straight away if you notice any of the following serious side effects - you may need urgent medical treatment:**

- If immediately after inhaling this medicine your breathing problem or wheezing gets worse and you become short of breath. This may occur in rare cases when using this medicine (may affect up to 1 in 1 000 people).
- If you experience an allergic reaction - 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 (angioedema) and a fall in your blood pressure that may cause dizziness. This may occur in rare cases when using this medicine (may affect up to 1 in 1 000 people).

- If after taking this medicine you experience eye pain or discomfort, blurred vision or red eyes, or if you see halos or coloured spots. This may occur in rare cases when using this medicine (may affect up to 1 in 1 000 people).

**Tell a doctor as soon as possible but do not stop using this medicine unless told to do so if you experience the following:**

- Chest pain (due to heart problems such as angina). This may occur in rare cases when using this medicine (may affect up to 1 in 1 000 people).

**Other side effects:**

**Uncommon** (may affect up to 1 in 100 people)

- 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** (may affect up to 1 in 1 000 people)

- Irregular heartbeat.
- Decreased levels of potassium in your blood (called 'hypokalemia') seen in blood tests.
- Blurred vision, dilated pupils, painful, stinging, or red eyes, swelling of the eyes, see colours or lights.
- Increased sweating.
- Dry throat, swelling of the throat.
- Difficulty in breathing or speaking due to a brief spasm of your vocal muscles.
- Rash, Itchy Rash, and/or Itching
- Diarrhoea, constipation, being sick (vomiting) or other problems with your digestive system.
- Swelling or inflammation of the mouth.
- Muscle cramps, muscle weakness and pain.
- Difficulty in passing water (urine).
- Feeling weak.
- Fall in blood pressure.
- Mood changes.

The following side effect can also happen but the frequency of this is not known (frequency cannot be estimated from the available data):

- A condition known as lactic acidosis which may cause stomach pain, hyperventilation, shortness of breath even though there may be improvement in your wheezing, cold feet and hands, irregular heartbeat or thirst.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Ipratropium bromide/salbutamol Neutec**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton, pouch and the single-dose container label after EXP. The expiry date refers to the last day of that month.

Keep single-dose containers in the outer pouch and carton in order to protect from light and moisture. Do not use this medicine if you notice that the liquid is discoloured. Use immediately after first opening the single-dose container. Each container is for single use only.

Discard any unused contents immediately after first use. Partly used, opened or damaged single-dose containers should be discarded.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Ipratropium bromide/salbutamol Neutec contains**

- The active substances are ipratropium bromide and salbutamol. Each 2.5 mL single-dose container contains 0.5 mg ipratropium bromide (as ipratropium bromide monohydrate) and 2.5 mg salbutamol (as salbutamol sulphate).
- The other excipients are: sodium chloride, hydrochloric acid 1 N (for pH adjustment) and water for injections.

### **What Ipratropium bromide/salbutamol Neutec looks like and contents of the pack**

Each single-dose container contains 2.5 mL of clear, colourless or almost colourless nebuliser solution.

Five single-dose containers are overwrapped in a pouch and packed in a carton box.

Ipratropium bromide/salbutamol Neutec is available in packs of 10, 20, 40, 60, 80 or 100 single-dose containers.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Neutec Inhaler Ireland Limited  
22 Northumberland Road, Ballsbridge  
Dublin 4, Co. Dublin  
D04 ED73  
Ireland

### **Manufacturer**

NextPharma Oy  
Niittyhaankatu 20  
33720 Tampere  
Finland

**This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:**

Sweden	Ipratropium bromide/salbutamol Neutec
Belgium	Ipratropium bromide/salbutamol Neutec 0,5 mg/2,5 mg verneveloplossing
Denmark	Ipratropiumbromid/salbutamol Neutec
Finland	Ipratropium bromide/salbutamol Neutec 0,5 mg / 2,5 mg per 2.5 ml sumutinliuos

Germany	Ipratropiumbromid/Salbutamol Neutec 0,5 mg/2,5mg Lösung für einen Vernebler
Iceland	Ipratropium bromide/salbutamol Neutec
Ireland	Ipratropium bromide/salbutamol Neutec 0.5 mg/2.5 mg per 2.5 ml nebuliser solution
The Netherlands	Ipratropiumbromide/salbutamol Neutec 0,5/2,5 mg per 2,5 ml, verneveloplossing
Norway	Ipratropium bromide/salbutamol Neutec
Spain	Ipratropio bromuro/salbutamol Neutec 0,5 mg/2,5 mg solución para inhalación por nebulizador
United Kingdom (Northern Ireland)	Ipratropium bromide/salbutamol Neutec 0.5 mg/2.5 mg per 2.5 ml nebuliser solution

**This leaflet was last revised in 05/2023**