

## Package leaflet: Information for the patient

### Ipratropium bromide/salbutamol Azure 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 further questions, ask your doctor or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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

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

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

The name of your medicine is Ipratropium bromide/salbutamol Azure 0.5 mg/2.5mg per 2.5 ml Nebuliser Solution. You use it with a device called a ‘nebuliser’. This changes your medicine into a mist for you to breathe in. Ipratropium bromide/salbutamol Azure contains two different medicines called:

- ipratropium bromide and
- 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.

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

##### **Do not use Ipratropium bromide/salbutamol Azure if:**

- you are allergic (hypersensitive) to ipratropium bromide or salbutamol or any of the other ingredients of this medicine (listed in section 6)
- you are allergic to similar medicines that 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’).

Do not use if any of the above apply to you.

If you are not sure, talk to your doctor or pharmacist before using Ipratropium bromide/salbutamol Azure.

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

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.

Talk to 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 have 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.

If you are not sure if any of these apply to you, talk to your doctor or pharmacist before using Ipratropium bromide/salbutamol Azure.

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

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. This includes herbal medicines.

This is because Ipratropium bromide/salbutamol Azure can affect the way some other medicines work. Also, some other medicines can affect the way Ipratropium bromide/salbutamol Azure 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
- other 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 heartbeat or heart failure.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using Ipratropium bromide/salbutamol Azure.

### **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 Ipratropium bromide/salbutamol Azure to the doctor, dentist or anaesthetist.

### **Tests**

If you have to provide a 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 Ipratropium bromide/salbutamol Azure contains salbutamol and this may lead to a positive result.

### **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 or pharmacist for advice before taking this medicine. Do not use Ipratropium bromide/salbutamol Azure if you are pregnant, likely to get pregnant or are breast-feeding unless your doctor decides that the benefit to you outweighs any risk to your child.

### **Driving and using machines**

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

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

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

Ipratropium bromide/salbutamol Azure is for inhalation use. The solution is for inhalation after nebulisation.

The recommended dose for **adults (including the elderly)** is:  
the contents of one ampoule, three or four times a day.

The treatment with the nebuliser solution should always be started with the lowest recommended dose. In very severe cases two single-dose ampoules may be required for symptom relief. Administration should be stopped when sufficient symptom relief is achieved.

Ipratropium bromide/salbutamol Azure is not recommended for children.

Ipratropium bromide/salbutamol Azure has not been studied in patients with liver or kidney impairment and should be used with caution in these patient populations.

### **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.

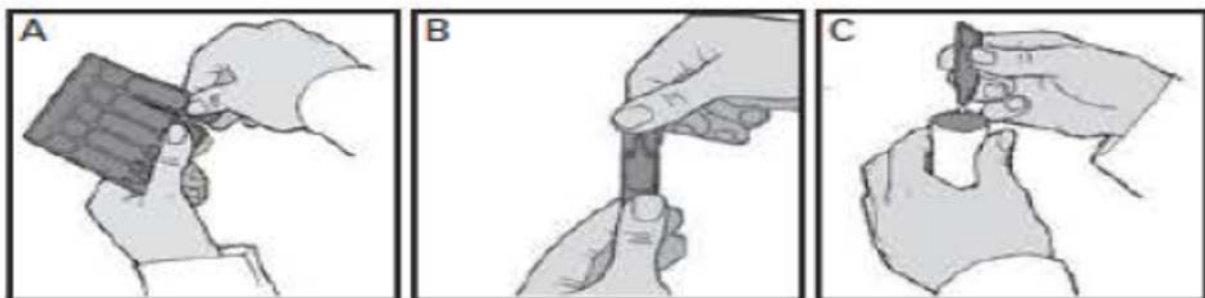
Your doctor may need to check how well your medicine is working. In some cases your doctor may need to change your medicine.

Ipratropium bromide/salbutamol Azure should be used with a suitable nebuliser, e.g. PARI Turboboy Nebuliser, jet nebuliser. Please read the full instructions for use of the nebuliser in the leaflet provided with PARI Turboboy before starting the inhalation.

### **Instructions for Use**

Read through instructions first, before starting to use your nebuliser.

- Prepare your nebuliser for use according to the manufacturer's instructions and advice from your doctor.
- Carefully remove an ampoule from the labelled strip by twisting and pulling. Never use an ampoule that has been opened already or if the solution is discoloured (diagram A).
- Hold the ampoule upright and twist off the cap (diagram B).
- Squeeze the contents into the reservoir of your nebuliser (diagram C).
- Follow the manufacturer's instructions and the advice from your doctor on how to assemble and how to use your nebuliser.
- After you have used your nebuliser, throw away any solution that is left in the reservoir. Any solution left in the ampoule should also be thrown away.
- Clean your nebuliser thoroughly according to the manufacturer's instructions. It is important that the nebuliser is kept clean.



Do not dilute the solution or mix it with other medicines, unless your doctor tells you to.

The single dose ampoules of Ipratropium bromide/salbutamol Azure do not contain preservatives and therefore it is important to use the contents immediately after opening. A new ampoule must be used each time you use Ipratropium bromide/salbutamol Azure in your nebuliser.

Partly used, opened or damaged ampoules should be discarded. You should never use an ampoule, which has been opened earlier.

It is important that you follow these instructions in order to avoid any contamination of the nebuliser solution within the ampoules.

**Do not** swallow the solution or use it in injections. **Do not** allow the solution or mist to enter your eyes.

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 use more Ipratropium bromide/salbutamol Azure than you should**

If you use more of this medicine than you should and experience symptoms such as fast heartbeat, chest pain, palpitations, tremor or flushing, discontinue treatment and talk to a doctor or go to a hospital straight away.

**If you forget to use Ipratropium bromide/salbutamol Azure**

If you forget to take a dose at the right time, take it as soon as you remember.

However, if it is time for the next dose, skip the missed dose. Do not take two doses together.

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

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

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

**Tell your doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:**

- If after taking Ipratropium bromide/salbutamol Azure 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.

The following side effect can also happen but the frequency of this is not known:

- 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.

The side effects described below have been experienced by people taking ipratropium bromide/salbutamol.

**Uncommon** (affects less than 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** (affects less than 1 in 1,000 people)

- irregular heartbeat
- 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.

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

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.

### **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: HPRA 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 Azure**

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 ampoule label after EXP. The expiry date refers to the last day of that month.

- For single use only. Use immediately after first opening the ampoule. Discard immediately after first use.
- Partly-used, opened or damaged ampoules should be disposed in accordance with local requirements.

Do not freeze. Keep single-dose containers in the outer pouch and carton in order to protect from light. After the opening of the pouch use within 7 days.

Do not take this medicine if you notice the solution is discoloured or cloudy.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer require. These measures will help protect the environment.

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

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

- The active substances are ipratropium bromide and salbutamol. Each single dose ampoule (2.5 ml) contains: 0.5 mg of ipratropium bromide (as monohydrate) and 2.5 mg salbutamol (as sulfate).

- The other ingredients are: sodium chloride, hydrochloric acid (for pH adjustment) and water for injections.

**What Ipratropium bromide/salbutamol Azure look like and contents of the pack**

LDPE single-dose containers containing 2.5 ml of clear, colourless or almost colourless solution.

Five LDPE single-dose containers are overwrapped in a laminated pouch (PET/Al/PE) and packed in a carton box.

Pack sizes of 20, 30 or 60 single-dose containers.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

Azure Pharmaceuticals Ltd, 12 Hamilton Drive, The Rock Road, Blackrock, Co. Louth, A91 T997, Ireland.

**Manufacturer**

Genetic S.p.A., Contrada Canfora, Fisciano, 84084, Italy.

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Ireland Ipratropium bromide/salbutamol Azure 0.5 mg/2.5 mg per 2.5 ml Nebuliser Solution

Malta Ipratropium bromide/salbutamol Azure 0.5 mg/2.5 mg per 2.5 ml Nebuliser Solution

**This leaflet was last revised in February 2026.**