

**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986**

This medicine is dispensed with a doctor's prescription only

## **Airways Respiratory Solution**

### **Active ingredient**

Each 1 ml (20 drops) contains:

ipratropium bromide 0.25 mg

Inactive ingredients and allergens: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

**Read the entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

### **1. What is this medicine intended for?**

Relieving symptoms of reversible bronchospasm associated with asthma, chronic bronchitis, and emphysema. Airways is of particular benefit in relieving acute bronchospasm when used concomitantly with inhaled beta agonists.

**Therapeutic group:** anticholinergic.

### **2. Before using this medicine**

**Do not use this medicine if:**

- You are sensitive (allergic) to the active ingredient ipratropium bromide, to atropine or atropine derivatives (anticholinergic active ingredients with similar structure) or to any of the other ingredients in this medicine (listed in section 6).

### **Special warnings about using this medicine**

Consult with your doctor or pharmacist before using this medicine.

- Exercise caution to ensure that the solution or inhalation mist does not come into contact with your eyes. Special caution should be used when using Airways in patients with a tendency to narrow-angle glaucoma. If the medicine accidentally comes into contact with your eyes during use, mild and reversible eye complications may occur. Especially in patients with elevated intraocular pressure (narrow-angle glaucoma), who may experience an acute glaucoma attack with the following characteristic symptoms: eye pain, blurred vision, cloudy vision, seeing halos around lights or seeing colors incorrectly, red eyes, and swelling of the cornea.
- When there is pupil dilation with mild temporary problems adjusting to different distances (accommodation problems), this can be treated with eye drops that make your pupils smaller. In the event of serious eye complications, consult an eye doctor. In these patients, if possible, a mouthpiece and not a face mask should be used during inhalation to prevent the medicine from getting into the eyes.
- Exercise extra caution in patients with impaired bladder function (for example in patients with an enlarged prostate or narrowed bladder neck).
- Dysfunction and motility disorders of the digestive system can occur in patients with cystic

fibrosis. If breathing difficulty gets acutely worse while inhaling the medicine (paradoxical bronchospasm), stop treatment immediately and contact your doctor to change your treatment regimen.

- Immediate hypersensitivity reactions may occur after use of Airways such as rare cases of skin rash (exanthema), hives (urticaria), severe allergic reaction (anaphylactic shock) as well as significant swelling (angioedema) of the tongue, lips and face, and tightening of the airway muscles (bronchospasm).

### **Interactions with other medicines**

**If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.**

- Long-term use of other medicines that are similar to ipratropium bromide (anticholinergic) together with Airways has not been studied and is therefore not recommended.
- Beta agonists and medicines that contain xanthine (such as theophylline) can enhance the effect of the medicine.
- Other anticholinergics, such as pirenzepine-containing medicines can enhance the effect of the medicine and its side effects.
- The risk of an acute glaucoma attack in patients with narrow-angle glaucoma may increase when Airways is used concomitantly with beta-mimetics.

### **Using this medicine and food**

No restrictions.

### **Pregnancy, breastfeeding and fertility**

#### Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, do not use this medicine before you consult your doctor or pharmacist.

There is no information about using this medicine in humans during pregnancy and breastfeeding. Although currently no known teratogenic effects have been reported, Airways can only be used during pregnancy, especially during the first trimester of the pregnancy and during breastfeeding, if your doctor considers the treatment essential.

The risk of inappropriate treatment should be considered.

#### Fertility

There is no clinical information about fertility in connection with ipratropium bromide (the active ingredient in Airways). Pre-clinical studies with ipratropium bromide did not show any negative effect on fertility.

### **Driving and using machines**

No studies have been conducted on the effects of this medicine on the ability to drive or operate machines. During treatment with this medicine, side effects such as dizziness, problems with your eyes adjusting to distances (accommodation problems), temporary pupil dilation (mydriasis), and blurred vision may appear. Therefore, exercise caution when driving and using machines. Caution children against riding a bicycle, playing near a road and similar activities.

### **Important information about some of this medicine's ingredients**

This product contains the preservative benzalkonium chloride (0.1 mg/ml). Benzalkonium chloride may cause wheezing and breathing difficulties (bronchospasm - sudden narrowing of the airway), especially if you have asthma.

### **3. How to use this medicine?**

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

The recommended dosage is usually:

Adults and children above 12 years of age:

0.1-0.5 mg (0.4-2.0 ml = 8-40 drops) up to 4 times a day

Children:

6-12 years: 0.25 mg (20 drops, meaning 1 ml) 3 to 4 times a day

Children under 6 years of age:

Since there is limited information regarding this age group, take according to the following dosage regimen under medical supervision. A single inhalation dose of 0.1-0.25 mg (8-20 drops, meaning 0.4-1.0 ml).

Use this medicine at set intervals, as determined by your doctor.

#### **Please note!**

This medicine is not intended for swallowing.

Avoid contact with the eyes. In case of harm to the eyes, rinse with plenty of water.

#### **Directions for use**

Drip from the bottle directly into the inhalation device and then dilute with the appropriate amount of sterile physiological solution, according to the inhalation device and your doctor's instructions.

#### **How can you contribute to the success of the treatment?**

Even if your health improves, do not stop taking this medicine without consulting your doctor.

#### **Do not exceed the recommended dose.**

#### **If you have accidentally taken a higher dose**

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. If the dosage required is exceeded significantly, seek medical attention immediately. You may be at greater risk of experiencing side effects such as dry mouth, problems with your eyes adjusting to distances (accommodation problems) and rapid heart rate.

#### **If you forget to take the medicine**

If you forget to take the medicine at the scheduled time, take a dose as soon as you remember, but under no circumstances should you take two doses together! Do not take a double dose to make up for a forgotten dose. Inhale the next dose at the usual time. If you consistently fall short of the dosage, your shortness of breath may get worse.

#### **Adhere to the treatment as recommended by your doctor.**

Your doctor will determine the duration of treatment based on your current medical condition. Talk to your doctor or pharmacist if you feel the effect of Airways is too strong or too weak.

#### **If you stop taking this medicine**

Interrupting or ending Airways treatment early may lead the disease to worsen.

**Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.**

**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

#### **4. Side effects**

As with any medicine, using Airways may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

##### **Common side effects - effects that occur in 1-10 in 100 users:**

- headache
- dizziness
- cough
- throat irritation
- dry mouth
- taste disturbances
- gastrointestinal motility disorders
- nausea.

##### **Uncommon side effects - effects occurring in 1-10 in 1,000 users:**

- immediate hypersensitivity reactions
- blurred vision
- temporary pupil dilation
- increased intraocular pressure sometimes with eye pain
- seeing haze and rainbow colors (auras)
- increased circulation to the conjunctiva
- corneal swelling
- glaucoma
- Stronger heart beat (palpitations)
- supraventricular cardiac arrhythmia with increased heart rate (inhalation-induced)
- bronchospasms (tightening of the bronchial muscles)
- tightening of the vocal cord muscles
- swelling of the throat
- dry throat
- constipation
- diarrhea
- abdominal pain
- vomiting
- inflammation of the lining of the mouth
- swelling of the mouth
- rash
- itching
- significant swelling of the tongue, lips and face
- urinary retention.

##### **Rare side effects - effects that occur in 1-10 in 10,000 users:**

- eyes have problems adjusting to distances (accommodation problems)
- atrial fibrillation
- hives.

As with all medicines for inhalation, some patients may experience signs of local irritation in the throat area.

**If you experience any side effect, if any side effect gets worse or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

### **Reporting side effects**

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)), which opens an online form for reporting side effects, or you can also use this link:  
<https://sideeffects.health.gov.il>

## **5. How to store the medicine?**

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the label and carton. The expiry date refers to the last day of that month.

### **Storage conditions:**

- Store this medicine below 25°C. Protect from light. Do not freeze.
- Do not use Airways Respiratory Solution for more than one month after the first opening of the bottle. Prepare fresh solution before each use. After use, dispose of any remaining solution. Do not throw away any medicine via wastewater (such as the toilet or sink). At the pharmacy, ask how to dispose of medicines you no longer use. These measures will help protect the environment.

## **6. Additional information**

- **In addition to the active ingredient, this medicine also contains:**  
purified water, sodium chloride, hydrochloric acid, disodium edetate, benzalkonium chloride.
- **What the medicine looks like and contents of the pack:**  
A brown glass bottle with a dropper mouthpiece that contains 20 ml of clear color-free solution. Child-resistant package.
- **Registration holder's and manufacturer's name and address:** Sam-On Ltd., 25 Ehud Kinamon (Haavoda), Bat Yam

Revised in July 2023 according to Ministry of Health guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry:  
173-12-36642-99