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

This medicine is dispensed with a doctor's prescription only

Aerovent®

Respirator solution

Every 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.
AEROVENT is particularly effective in relieving acute bronchial constriction when given together 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 substances with similar structure) or to any of the other ingredients in this medicine (listed in section 6).

Special warnings about using this medicine
Consult your doctor or pharmacist before using this medicine.
Talk to your doctor before treatment with AEROVENT if:

- Care must be taken to ensure that the solution or the mist from the nebulizer does not get into the eyes. AEROVENT should be used with special care in patients with a tendency to narrow-angle glaucoma. If the medicine accidentally gets in your eyes while you are using it, slight and reversible eye complications can occur. In patients with elevated intraocular pressure (narrow angle glaucoma) particularly, there is a possibility of an acute glaucoma attack, with the following typical symptoms: eye pain, blurred vision, cloudy vision, seeing halos around lights or unreal perception of color, red eyes, and swelling of the cornea.
- You have pupil dilation with mild and temporary difficulty adjusting to different distances (accommodation problems), this condition can be treated with eye drops that contract your pupils. Contact an eye doctor if you experience serious eye complications. If possible, these patients should use a

mouthpiece and not a face mask for inhalation, so that the medicine does not get in their eyes.
- Use with caution in patients with impaired bladder function (for example in patients with an enlarged prostate or bladder neck obstruction).
- 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.
- Immediate hypersensitivity reactions, such as rare cases of skin rash (exanthema), hives (urticaria), shock-like allergic reactions (anaphylaxis), as well as significant swelling (angioedema) of the tongue, lips and face, and tightening of the muscles of the bronchial tubes (bronchospasm), may occur after using AEROVENT.

Drug interactions
If you are taking, may be taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:
- Long-term use of AEROVENT with other medicines that are similar to ipratropium bromide (anticholinergics) has not been studied and is therefore not recommended.
- Beta-adrenergic medicines and xanthine medicines (such as theophylline) may increase the effect of this medicine.
- Other anticholinergic agents, such as medicines containing pirenzepine, may increase the effect and side effects of this medicine.
- The risk of an acute glaucoma attack in patients with narrow-angle glaucoma may be increased when AEROVENT and beta-mimetics are used together.

Please note that this information may also apply to medicines you have recently taken.

Using this medicine with food and drink
There are no restrictions.

Pregnancy, breastfeeding, and fertility
Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

There is no information about using this medicine in humans during pregnancy and breastfeeding.
Although so far no known teratogenic effects have been reported, AEROVENT should only be used in pregnancy, especially during the first three months of pregnancy and during breastfeeding, if deemed necessary by your doctor.
The risk from inappropriate treatment should be considered.

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

Driving and using machines
There have been no studies on the effects of this medicine on the ability to drive and the ability to use machines.

During treatment with this medicine you may experience side effects such as dizziness, problems with your eyes adjusting to distances (accommodation problems), temporary pupil dilation (mydriasis), and blurred vision. Therefore, exercise caution when driving and using machines. With respect to children, they should be warned against riding bicycles or playing near roads, etc.

Important information about some of this medicine's ingredients
This product contains the preservative benzalkonium chloride (0.1 mg/ml). Benzalkonium chloride can cause wheezing and breathing difficulties (bronchospasms - sudden constriction of the airways), 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:
0.1-0.5 mg (0.4-2.0 ml = 8-40 drops) up to 4 times a day

Children:
6-12 years old: 0.25 mg (20 drops which are 1 ml) 3 to 4 times a day

Children under 6 years old:
Since only limited information in this age group is available, the following dosage must be given under medical supervision:
a single inhaled dose of 0.1–0.25 mg (8-20 drops which are 0.4-1.0 ml)

Use this medicine at the regular intervals prescribed by your doctor.

Note!
This medicine is not for swallowing.
Avoid contact with the eyes. In case of contact with the eye, rinse with plenty of water.

How to use this medicine
Apply the drops directly from the bottle into the nebulizer and then dilute with a suitable amount of sterile physiological saline depending on the nebulizer and according to your doctor's instructions.

How can you contribute to the success of your treatment?
Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not exceed the recommended dose.

Do not swallow.

If you have accidentally taken a higher dose

If you have taken an overdose, or if a child has accidentally inhaled some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. If you significantly exceed the prescribed dose, 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 increased heart rate.

If you forget to take the medicine
If you forget to take this medicine at the scheduled time, take it as soon as you remember, but never take two doses together! **Do not take a double dose to make up for a forgotten dose**. Inhale the next dose at the scheduled time.
If you take continuous low dosage of this medicine, your shortness of breath may get worse.

Adhere to the treatment as recommended by your doctor.
Your doctor will decide on the duration of treatment based on your present medical condition. Please consult your doctor or pharmacist if you feel that the effect of AEROVENT respirator solution is either too strong or too weak.

If you stop taking this medicine
If you interrupt or end your AEROVENT treatment early, your illness may get worse.

Do not take medicines in the dark! Check the label and dose <u>every time</u> 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. <u>Side effects</u>

Like with all medicines, using AEROVENT 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 (affect 1-10 in 100 users):
- headache,
- dizziness,
- cough,
- throat irritation,
- dry mouth,
- taste disturbances,
- gastrointestinal motility disorders,
- nausea.

Uncommon side effects (affect 1-10 in 1,000 users):
- immediate hypersensitivity reactions,
- blurred vision,
- temporary pupil dilation,
- increased intraocular pressure sometimes with eye pain,
- foggy vision and rainbow colors (halos),
- increased circulation to the conjunctiva,
- corneal swelling,
- glaucoma,

- increased heart beat (palpitations),
- supraventricular cardiac arrhythmia with increased heart rate (inhalation-related),
- bronchospasms (muscle spasm of the airways),
- muscle spasms of the vocal cords,
- swelling of the throat,
- dry throat,
- constipation,
- diarrhea,
- stomach pain,
- vomiting,
- inflammation of the oral mucosa,
- swelling of the mouth,
- skin rash,
- itching,
- significant swelling of the tongue, lips and face,
- urinary retention.

Rare side effects (affect 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 link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. 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 a 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:

- Keep this medicine below 25°C. Do not freeze.

- Do not use AEROVENT respirator solution for longer than one month after first opening the bottle. Prepare a fresh solution before every use. After use, discard any remaining solution. Do not discard any medicine via wastewater (e.g. down the toilet or washbasin). Ask at your pharmacy how to throw away 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, 1 N hydrochloric acid, disodium edetate dihydrate, benzalkonium chloride

- What the medicine looks like and contents of the pack:
  a 20 ml glass bottle with dropper.

- Manufacturer: Istituto de Angeli S.R.L., Localita Prulli di Sotto 103/C, 50066 Reggello, Italy

- Registration holder: Boehringer Ingelheim Israel Ltd., 89 Medinat Hayehudim Street, P.O.B. 4124, Herzeliya Pituach 4676672.

This leaflet was revised in January 2022 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 055 80 27113 01