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

This medicine is dispensed with a doctor's prescription only

ATROVENT®

Inhaler

Each puff releases: 0.02 milligram ipratropium bromide

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 to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is this medicine intended for?

Relieving symptoms of reversible bronchospam in cases of asthma, chronic bronchitis, and emphysema.

Therapeutic group: anticholinergic.

ATROVENT is an inhaler that dilates the airways in cases of bronchospasm (constriction of the bronchial walls), so that you can breathe freely more easily.

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 substances with similar structure) or to any of the other ingredients in this medicine (listed in section 6).
- You are pregnant (particularly during the first three months) or are breastfeeding, unless your doctor has recommended this treatment after weighing the risks and benefit.

Special warnings about using this medicine

- Talk to your doctor or pharmacist before using this medicine.
- Make sure that the solution or medicine mist does not get in your eyes.
- Use ATROVENT with caution if you have a tendency to narrow-angle glaucoma.
  If the medicine accidentally gets in 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.
- If you have pupil dilation with mild temporary problems adjusting to different distances (accommodation problems), this condition can be treated with eye drops that make your pupils smaller. Contact an eye doctor if you experience

serious eye complications.
Since the inhaler is used with a mouthpiece and is manually-controlled, the chance of spraying the medicine into your eyes is small.

- Use with caution in patients with bladder-emptying disorders (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.
- Immediate hypersensitivity reactions may occur after using this medicine such as rare cases of skin rash (exanthema), hives (urticaria), anaphylactic shock and significant swelling (angioedema) of the tongue, lips and face, and tightening of the airway muscles (bronchospasm).

Children and adolescents
See section 3: 'How to use this medicine?'.

Other medicines and ATROVENT
If you are 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 ATROVENT with other medicines that are similar to ipratropium bromide (anticholinergic) has not been studied and is therefore not recommended.
- Beta agonists and medicines that contain xanthine (such as theophylline) can enhance the effect of ATROVENT.
- Other anticholinergics, such as pirenzepine-containing medicines can enhance the effect of ATROVENT and its side effects.

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

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 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 currently this medicine is not known to have any teratogenic effects, it should only be used during pregnancy, especially during the first trimester and during breastfeeding, if your doctor considers it necessary and has made a careful risk-benefit assessment.
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 ATROVENT). Pre-clinical studies with ATROVENT (ipratropium bromide) did not show any negative effect on fertility.

Driving and using machines

There are no studies on the effect of this medicine on ability to drive or operate 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.
Caution children against riding a bicycle, playing near a road, and similar activities.

Important information about some of this medicine's ingredients
This medicine contains a small amount of alcohol (less than 100 mg in one puff).

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. It is important to follow the instructions for using ATROVENT. Proper use of the inhaler is necessary for your treatment to succeed. 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:
One or two puffs, four times a day, although some patients may need up to four puffs a day when they start treatment to get the most benefit. Do not exceed a dosage of 12 puffs in 24 hours.

Children:
6-12 years old: one or two puffs, three times a day.
To ensure correct use of the inhaler, children should inhale ATROVENT under adult supervision.
The same dose recommendations apply to children under 6 years old. Since currently there is insufficient experience using this medicine in this age group, inhalation of ATROVENT should be supervised by a doctor.

Use in children must be supervised by an adult.

If additional treatment is needed and your dose is increased, do not exceed a total daily dose of 12 puffs.
Do not exceed the recommended dose.

This medicine is for inhalation only.

How to use your ATROVENT inhaler:
If possible, use this medicine while sitting or standing.
Correct use of the medicine is essential for your treatment to succeed.
Test fire the inhaler twice into the air to prime it before you use it for the first time.
If you have not used your inhaler for longer than 3 days, prime it by firing one puff into the air.
Follow the instructions below with **every** use:
1. Remove the protective cap (Figure 1).

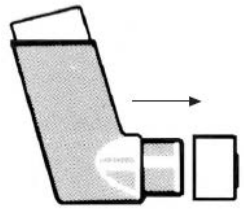


Figure 1

2. Breathe out deeply.
3. Hold the inhaler in one hand and place your lips firmly around the mouthpiece (Figure 2).

(Figure 2)

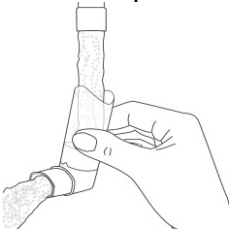
4. While breathing in as deeply as you can, firmly depress the metal canister to release one metered dose (Figure 3). Make sure you breathe in while you are pressing the metal canister. Hold your breath for a few seconds, then remove the mouthpiece from your mouth and breathe out slowly.

(Figure 3)

5. Replace the protective cap.

Do not spray in or around the eyes.

Clean your inhaler once a week, as follows:
It is important to keep the mouthpiece of your inhaler clean to ensure that the medicine does not build up and block the spray.
To clean it, first take off the protective cap and then separate the metal canister from the mouthpiece. Rinse the mouthpiece with warm water until it is clean.



Shake the mouthpiece after cleaning and allow to air dry. Once the mouthpiece is dry, re-insert the canister and replace the protective cap.

It is easier to keep the mouthpiece clean if you do not breathe into the inside of the mouthpiece.
The mouthpiece was specially developed for use with this inhaler to ensure that the correct dose is always released. Do not use this mouthpiece with other inhalers. Only use this medicine with the mouthpiece supplied with it and not with any other mouthpiece.

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.
Do not take more than 12 metered doses (puffs) a day. In addition, a total daily dose of more than 12 puffs does not usually provide any additional therapeutic benefit. 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
Do not take a double dose to make up for a forgotten dose. Inhale the next dose at the regular time.
If you consistently fall short of the prescribed dose, 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 medical condition and the severity of your side effects. Do not change or stop treatment on your own initiative.
Talk to your doctor or pharmacist if you think the effect of the inhaler is too strong or too weak.
Even if your health improves, do not stop taking this medicine without consulting your doctor.
If you stop taking this medicine
If you interrupt or end your ATROVENT treatment early, your shortness of breath may get worse. Therefore, do not stop your ATROVENT treatment without talking to your doctor first.

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 ATROVENT 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 (frequency range is 1:10 to 1:100):
headache, dizziness, cough, throat irritation, dry mouth, taste disturbances, gastrointestinal motility disorders, and nausea.

Uncommon (frequency range is 1:100 to 1:1000):

immediate allergic reactions, hypersensitivity reactions, blurred vision, temporary pupil dilation, increased intraocular pressure sometimes with eye pain, seeing haze and rainbow colors (rainbow colored rings), 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 throat muscles, swelling of the throat, dry throat, constipation, diarrhea, abdominal pain, vomiting, inflammation of mouth, swelling of the mouth, skin rash, itching, significant swelling of the tongue, lips and face, urinary retention.

Rare (frequency range is 1:1000 to 1:10000):
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 package and label. The expiry date refers to the last day of that month.

Storage conditions:
Store below 30˚C. Protect from direct sunlight.
The medicine canister contains pressurized liquid. Do not expose to temperatures higher than 50°C. Do not puncture the canister.
Do not throw away the inhaler with the propellant via wastewater (e.g. down the toilet or washbasin) and do not dispose of it in the household waste. Ask at your pharmacy how to throw away medicines you no longer use. These measures will help protect the environment.

Shelf-life after first opening: to the end of the medicinal product's shelf-life.
Warning: Pressurized container: Do not puncture, break, or burn even if empty.

6. Additional information

- In addition to the active ingredient, this medicine also contains:
  citric acid, anhydrous, purified water, ethanol (absolute 99%), propellant HFA 134A (1,1,1,2-tetrafluoro-ethane)

- What the medicine looks like and contents of the pack:
  10 ml (200 metered doses) metal canister that is a part of a plastic inhaler with mouthpiece.

- Manufacturer: Boehringer Ingelheim Pharma GmbH & Co. KG, 173 Binger street, D-55216 Ingelheim am Rhein, Germany.

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

This leaflet was revised in November 2020.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 130-01-30934-00.