

## Patient leaflet in accordance with the pharmacists' regulations (preparations) 1986

This medicine is to be supplied upon physician's prescription only

# Atrovent®

Inhaler

Each inhalation releases 0.02 mg Ipratropium Bromide.



Boehringer  
Ingelheim

Inactive Ingredients and allergens: See section 6.

**Carefully read the package insert in its entirety before using the medicine.** This leaflet contains summary information about this medicine. If you have any further questions, refer to your physician or the 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.

ATROVENT is an inhaler that dilates the airways in cases of bronchospasm (constriction of the bronchial walls), thus helping you to breathe more easily and freely. This medicine is not intended for use in children under 6 years of age.

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

To relieve the symptoms of reversible bronchospasm in cases of asthma, chronic bronchitis or emphysema.

**Therapeutic group:** Anticholinergic.

### 2. Before using this medicine

#### Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient, or to any of the other ingredients of this medicine, or to atropine or atropine derivatives (anticholinergic substances with similar structure).

#### Special warnings regarding the use of the medicine

- The preparation is not indicated as first line treatment for acute bronchospasm attacks.
- Avoid product contact with the eyes. If during use the medicine comes into accidental contact with the eyes, you may suffer slight, reversible eye complications. Patients suffering from narrow angle glaucoma may experience severe glaucoma attacks accompanied by the following symptoms: eye pain, blurred vision, cloudy vision, halos around light points or changes in color perception, redness of the eye and swelling of the cornea. If following contact between the medicine and your eyes you suffer from widened pupils with slight, temporary difficulties in focusing at various distances (accommodation problems), this can be treated with eye drops that contract the pupils. In the event of serious eye complications, consult an ophthalmologist.
- Since the measured dose is delivered directly into the mouth and manually controlled, the chances of accidentally spraying the preparation into the eye are low.
- If while taking this medicine your breathing difficulties become more severe (paradoxical bronchospasm) you must stop the treatment immediately and consult your physician who will review your treatment plan.
- Immediate allergic reactions may occur after use of this medicine. These reactions include: rare cases of skin rash (redness), itching (urticaria), anaphylactic shock and swelling (angioedema) of the tongue, lips and face, and muscle spasms of the airways (bronchospasm).

#### Before using ATROVENT tell your physician if:

- You suffer or have previously suffered from defective eye function.
- You suffer or have suffered from urinary tract problems (for example, enlarged prostate). In this case caution should be used.
- You suffer from cystic fibrosis. Cystic fibrosis patients may experience problems with their digestive system.

If you are not sure whether any of the above points applies to you, consult your physician or the pharmacist before taking the medicine.

**If you are taking or have recently taken other medicines, including nonprescription medications and food supplements, inform your physician or pharmacist.** In particular inform the physician or the pharmacist if you are taking:

- Beta 2 adrenergic agonists, xanthines and their derivatives (such as theophylline). These medicines may increase the effect of ATROVENT.
- Other anticholinergic preparations, such as preparations containing pirenzepine, may increase the effect of ATROVENT and the side effects.

#### Using the medicine and food

There are no restrictions on the use of this medicine with any food or drink.

#### Pregnancy and breastfeeding

You should consult a physician or pharmacist before taking any medicines.

Although this medicine is not known to have any teratogenic effects, it should not be used during pregnancy, particularly in the first trimester, and while breastfeeding only if the physician considers it essential, after cautious consideration of the risks versus the benefits.

There is no information about use of this medicine by pregnant and lactating women.

#### Driving and using machines

No studies have been done on the effects of the medicine on the ability to drive or operate machinery.

You may experience side effects such as dizziness, accommodation disorder (difficulty in focusing), temporary pupil dilation and blurred vision during treatment with this medicine. Therefore, you should use caution while driving or operating machinery. If you experience any of the above side effects you should avoid dangerous activities such as driving or operating - machinery.

#### Important information about some of the ingredients of this medicine

- This medicine contains alcohol (less than 100 mg in one inhalation).
- This medicine does not contain Freon gas (CFC) and is therefore not harmful to the earth's ozone layer and is more environmentally friendly.

### 3. How should you use the medicine?

**The dosage and treatment will be determined only by the physician. Do not exceed the recommended dose.**

Always use according to the physician's instructions. It is important to be careful when using ATROVENT. Correct use of the inhaler is essential to the success of the treatment. The medicine is only delivered as an inhalant. You should check with the physician or the pharmacist if you are unsure.

#### How to use ATROVENT Inhaler:

If possible, use the preparation while sitting or standing.

Proper use of the preparation is essential to successful treatment.

Before the apparatus is used for the first time, prime it by pressing **twice into the air**.

After not using the metered Inhaler for 3 days, re-prime by pressing once into the air.

On each use, follow these instructions:

- Remove the protective cap (figure 1).



- Breathe out deeply.

- Hold the inhaler in your hand and close the lips tightly around the mouthpiece. (figure 2)



- Breathe in as deeply as possible and, at the same time, press the top of the metal container once to deliver one metered dose (figure 3)

Make sure that inhalation and pressing the metal container are carried out simultaneously.

Hold your breath for a few seconds. Remove the Inhaler and then breathe out slowly.



- Replace the protective cap.

#### Do not spray into or around the eyes.

#### The inhaler should be cleaned once a week as follows:

It is important that you keep the mouthpiece of the inhaler clean in order to ensure that no deposits of the medicine block the spray.

To clean the inhaler, first remove the protective cap then remove the container from the mouthpiece.



Rinse the mouthpiece under warm water until no dirt is visible.

Shake the mouthpiece after cleaning and allow to air dry. Once the mouthpiece is dry, replace the container and protective cap.



It is easier to keep the mouthpiece clean by avoiding breathing into it.

The mouthpiece was developed specifically for use with this inhaler to ensure that the correct dose is always released. It should not therefore be used with any other metered dose inhalers. Likewise, no mouthpiece should be used with the inhaler other than the one provided.

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

If you have taken an overdose, or if a child has accidentally swallowed the medicine, go immediately to a hospital emergency room and bring the medicine package with you. Side effects of overdose: dry mouth, problems of eye adjustment to various distances (accommodation problems) and rapid heart rate.

#### If you forget to take the medicine

**Do not take a double dose to compensate for the missed dose.** Take the next dose at the usual time. If you miss several doses, your shortness of breath may become worse.

Persist with the treatment as recommended by the physician. Your physician will determine your treatment plan based on your medical condition and the severity of any side effects. You must not change or stop the treatment without your physician's instructions. Your shortness of breath may get worse if you change or stop the treatment too soon.

You should consult your physician or the pharmacists if you feel that the effect of the inhaler is too strong or too weak.

Even if there is an improvement in your health, do not stop the treatment with the medicine without consulting the physician.

If despite of your treatment plan your condition has not been improved considerably or even worsen, you should consult your physician, as your treatment plan has to be reviewed. It may be necessary to include other drugs (corticosteroids, beta - adrenergic agonists drugs, theophylline) in your treatment plan. In the event of severe shortage of breath or rapid deterioration of your condition, seek medical treatment immediately.

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

If you have any further questions regarding the use of the medicine, consult the physician or the pharmacist.

#### 4. Side effects

As with any medicine, use of ATROVENT Inhaler may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

**Common (frequency between 1:10 to 1:100):** Headache, dizziness, cough, throat irritation, dry mouth, gastrointestinal problems and nausea.

**Uncommon (frequency between 1:100 to 1:1000):** Immediate allergic reaction, hypersensitivity, blurred vision, temporary pupil dilation, increased intraocular pressure, possibly accompanied by eye pain, clouded vision or colors (halos), increased blood flow to the conjunctiva, swollen cornea, glaucoma, heart palpitations, supraventricular tachycardia, bronchospasms (contractions of bronchial muscles), paradoxical bronchospasms due to use of inhalants, spasms of the pharyngeal muscles, swollen throat, dry throat, constipation, diarrhea, stomach ache, vomiting, mouth inflammation, swollen mouth, rash, itching, swollen tongue, lips and face (angioedema), urine retention.

**Rare (frequency between 1:1000 to 1:10000):** Problems of adjusting vision to different distances (accommodation problems), atrial fibrillation, rapid heart rate, urticaria.

As with any inhaled medication, some patients may experience localized irritation in the throat.

If any of the side effects gets worse, or if you experience a side effect not mentioned in the leaflet, you should consult your physician.

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

Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.

Do not use the medicine after the expiry date (exp. date) appearing on the carton and label. The expiry date refers to the last day of that month.

Store at a temperature below 30°C.

Protect from direct sunlight.

The medicine container contains liquid in pressure. Do not expose to temperature above 50 degrees Celsius. Do not puncture the container.

Shelf life after first use: Until end of shelf life of the preparation.

Warning! Pressurized container: Do not puncture, break or burn even when empty.

#### 6. Additional information

In addition to the active ingredient the medicine also contains:

1,1,1,2-tetrafluoroethane (propellant HFA 134a), ethanol absolute (99%), purified water, citric acid anhydrous.

What does the medicine look like and what are the contents of the package: A metal container containing 10 ml. (200 measured doses) as part of a plastic inhaler with a mouthpiece.

Registration holder: Boehringer Ingelheim Israel Ltd., 89 Medinat Ha-Yehudim St.

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This leaflet was checked and approved by the Ministry of Health in: 07.2014

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