Active ingredient: Ipratropium bromide

Read the whole of this package insert carefully before starting to use this preparation.

- Keep this leaflet. You may need to read it again.
- If you have any other questions please contact your doctor or pharmacist.
- This preparation was prescribed for you personally. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets troublesome or serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION is and what it is used for
2. Before you use ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION
3. How to use ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION
4. Possible side effects
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1. WHAT ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION IS AND WHAT IT IS USED FOR

Ipratropium bromide is a bronchodilator.

ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION is used:

For the prevention and treatment of dyspnoea associated with
- chronic obstructive pulmonary disease (COPD)
- mild or moderate asthma in adults and children, as a supplement to β2-agonists in an acute asthma attack.

2. BEFORE YOU USE ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION

Do not use ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION:

- if you are hypersensitive (allergic) to ipratropium bromide or any of the other ingredients of ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION, atropine or atropine derivatives (anti-cholinergic substances with a similar structure).
When must ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION be used only after consulting your doctor?

In the situations described below you may use ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION only under certain conditions and with particular caution. Ask your doctor for details, even if these situations have applied to you in the past.

If the medicine accidentally enters the eyes following incorrect use, this can cause mild, reversible ocular complications. Patients with increased intraocular pressure (narrow-angle glaucoma), in particular, may suffer an acute glaucoma attack with the following typical symptoms: eye pain, blurred vision, misty vision, coloured rings around light sources or an unreal colour sensation, reddened eyes and corneal swelling.

If the pupils become dilated and if mild, temporary problems with adjustment of the eyes to differing visual ranges (accommodation disturbances) should occur, these can be treated with eye drops that constrict the pupils (miotic eye drops). If serious ocular complications occur an ophthalmologist should also be consulted.

If possible, such patients should use a mouthpiece rather than a face mask during inhalation in order to prevent the medicine getting into the eyes.

ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION should be used with caution in patients with bladder-emptying problems (e.g. in patients with an enlarged prostate).

Disturbances in the function and motility of the gastrointestinal tract are prone to occur in patients with cystic fibrosis.

**Warnings**

If the breathing difficulties worsen suddenly during inhalation (paradoxical bronchospasm), the treatment must be stopped immediately and the treatment plan reviewed by the doctor.

Immediate-type hypersensitivity reactions can occur after the administration of ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION including e.g. rare cases of skin rash, (exanthema), nettle rash (urticaria), shock-like allergic reactions, severe swelling (angioedema) of the tongue, lips and face and spasm of the muscles in the bronchi (bronchospasm).

**Using ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION with other medicines**

Please tell your doctor or pharmacist if you are taking/using, or have recently taken/used, any other medicines, including medicines obtained without a prescription.

β-adrenergic agents and xanthine derivatives (e.g. theophylline) can potentiate the action of Atrovent.

Other anticholinergic agents, such as those containing pirenzepine, can potentiate the action and side effects of Atrovent.

Please note that the above can also apply to recently administered preparations.

**Using ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION with foods and drinks**

No restrictions apply.
Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking/using any medicines.

Although no harmful effects on the fetus are known, ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION should be used during pregnancy, particularly during the first three months, and breastfeeding only if the doctor considers it to be necessary after a careful risk-benefit analysis. Appropriate consideration should be given to the risks of inadequate treatment. No experience has been gained with the use of the preparation in humans during pregnancy and breast-feeding.

Driving and using machines

No studies have investigated the effects on the ability to drive or operate machinery. Adverse effects such as dizziness, problems with adjustment of the eyes to differing visual ranges (accommodation disturbances), temporary pupil dilation (mydriasis) and blurred vision may occur during treatment with ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION. Caution is therefore indicated when driving or using machines. Patients who experience the above-mentioned side effects should not drive or work with machinery.

3. HOW TO USE ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION

Always use ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Please observe the directions for use as ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION may otherwise not work correctly. ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION is intended for inhalation with a nebuliser only.

The dosage must be adapted to the individual patient. Unless otherwise prescribed, the following dosage recommendations apply:

For acute treatment

*Adults and children over 12 years:*

The inhaled single dose is 0.5 mg ipratropium bromide, corresponding to 1 unit dose vial. Repeated doses may be administered until the dyspnoea improves, and the interval between individual inhalations must be decided by your doctor.

For long-term treatment

*Adults and children over 12 years:*

1 unit dose vial 3 - 4 times a day.

A daily dosage of more than 2 mg ipratropium bromide (4 unit dose containers) should be reviewed regularly by your doctor.

The recommended daily dosage should not be exceeded, either for acute or long-term treatment.

Important note

If the prescribed therapy does not produce a satisfactory improvement, or if your condition gets worse, medical advice must be sought so that the treatment can be reviewed and, if necessary, supplemented with other preparations (corticosteroids, β₂-sympathomimetic drugs, theophylline). In the event of acute or rapidly worsening dyspnoea, medical help should be sought immediately.
**How and when should ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION be used?**

This solution is ready for use, i.e. no dilution is required. The solution in unit dose vials is for inhalation only using suitable inhalation devices and should not be drunk or injected. ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION can be used with proprietary nebuliser devices; if oxygen is administered the ideal flow rate is 6 – 8 l/min.

If possible, the preparation should be administered while you are sitting or standing.

**Instructions for use**

1. Prepare your inhalation device (nebuliser) according to the manufacturer's instructions and the advice of your doctor.

2. Separate a unit dose vial from the strip (see Fig.1)

![Fig. 1](image1)

3. Open the vial by twisting off the top (tear-off tab) (see Fig. 2).

![Fig. 2](image2)

4. Transfer the contents to the nebuliser chamber by repeated squeezing of the unit dose vial (see Fig. 3).

![Fig. 3](image3)
5. Reassemble the nebuliser and inhale the solution as directed.

6. After the inhalation, remove any remaining solution from the nebuliser chamber and clean the nebuliser according to the instructions.

Care must be taken to ensure that the solution or inhalation mist does not enter the eyes. The nebulised solution should be inhaled through a mouthpiece. If no mouthpiece is available and a nebuliser mask is used, you must ensure that it is correctly fitted. Patients who may be predisposed to glaucoma should take particular care to ensure that their eyes are protected during inhalation.

As the product contains no preservative the contents of the unit dose must be inhaled immediately after opening, and any remaining solution should be discarded.

A fresh unit dose vial should be used for each dose. Accidentally opened or damaged unit dose vials should be discarded.

ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION is suitable for concurrent inhalation with ambroxol, e.g. contained in Mucosolvan® solution for inhalation.

Atrovent 500 µg/2 ml SOLUTION FOR INHALATION and DSCG (disodium cromoglycate) solutions should not be inhaled simultaneously in the same nebuliser.

**For how long should ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION be taken?**

The duration of treatment will be decided by your doctor and will depend upon the prevailing state of your illness.

Consult your doctor or pharmacist if you think that the effect of Atrovent 500 µg/2 ml SOLUTION FOR INHALATION is too strong or too weak.

**What precautions must be observed?**

**If you use more ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION than you should**

If you have substantially exceeded the prescribed dose you should seek medical help immediately. You may be more likely to suffer side effects such as a dry mouth, problems with adjustment of the eyes to differing visual ranges and a faster heart rate.
If you forget to use ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION

Do not take a double dose to make up for a forgotten dose. Inhale the next dose at the specified time. If lower doses are regularly administered, there is a risk that the dyspnoea will increase.

If you stop taking ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION

An interruption or premature termination of treatment with ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION can lead to a deterioration of your illness.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION can cause side effects, although not everybody gets them.

The commonest (in 1 - 10 % of patients) side effects that have occurred during the administration of Atrovent are headache, dizziness, cough, throat irritation, dry mouth, altered taste, disturbances in the motility of the gastrointestinal tract and nausea.

Certain side effects can occur less commonly (in 0.1 - 1% of patients). These include: immediate-type allergic reactions, hypersensitivity reactions, blurred vision, temporary pupil dilation, increased intraocular pressure, possibly with eye pain, seeing mist or rainbow colours (rainbow rings), increased conjunctival circulation, corneal swelling, glaucoma, increased palpitations, supraventricular arrhythmia with increased heart rate, (inhalation-induced) bronchospasm (spasm of the muscles in the bronchi), spasm of the laryngeal muscles, throat swelling, dry throat, constipation, diarrhoea, abdominal pain, vomiting, inflammation of the oral mucosa, swelling of the mouth, skin rash, itching, severe swelling of the tongue, lips and face, urinary retention.

Certain side effects occur rarely (in 0.01 - 0.1% of patients). These include: Problems with adjustment of the eyes to differing visual ranges, atrial fibrillation in the heart, nettle rash.

As with all inhaled medicines, signs of local irritation in the throat can occur in some patients. Please tell your doctor or pharmacist if any of these side effects gets troublesome or serious, or if you notice any side effects not listed in this leaflet.

5. HOW TO STORE ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION

Keep medicines out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the unit dose vials and the carton. The expiry date refers to the last day of the month.

Storage conditions

Do not store above 30 °C, keep in the original carton.

Shelf life after opening
As the product contains no preservative the contents of the unit dose must be inhaled immediately after opening, and any remaining solution should be discarded. Accidentally opened or damaged unit dose vials should be discarded.

6. FURTHER INFORMATION

What ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION contains:

The active ingredient is: ipratropium bromide

2 ml of solution (contents of a unit dose vial) contains:
522 µg ipratropium bromide monohydrate (equivalent to 500 µg anhydrous ipratropium bromide)

The other ingredients are:
sodium chloride, 3.6 % hydrochloric acid (for pH adjustment), purified water

What ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION looks like and contents of the pack:

Clear, colourless solution for a nebuliser
Pack containing 10, 20 or 50 unit dose vials of 2 ml

Marketing authorisation holder

Boehringer Ingelheim Pharma GmbH & Co. KG
Binger Str. 173
55216 Ingelheim am Rhein

Manufacturer

Laboratoire Unither
ZI de Longpré
10 rue Andre Durouchez
80084 Amiens Cedex 2
France

This leaflet was last revised in May 2012.

Keep medicines out of the sight and reach of children.

Properties

ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION is a preparation specifically for the prevention and treatment of dyspnoea in chronic obstructive bronchitis and mild or moderate asthma, as a supplement to β2-agonists in an acute asthma attack. As a result of the site of action of the active ingredient, ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION, an anticholinergic drug, inhibits spasms of the bronchial muscles triggered by the vagus nerve. This differentiates Atrovent from most other antispasmodic inhaled preparations.

ATROVENT 500 µg/2 ml SOLUTION FOR INHALATION dilates the airways. Regular administration can protect against constriction of the airways and spasm of the bronchial muscles.
Description of the dosage form
Clear, colourless solution

Other pharmaceutical forms
ATROVENT 250 µg/2 ml SOLUTION FOR INHALATION, solution for a nebuliser

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Boehringer Ingelheim
Middle East & North Africa
(Scientific Office) FZ-LLC
P.O. Box 505123
Dubai Healthcare City
Dubai, UAE.
Tel: +971 (4) 423 0400
Fax: +971 (4) 423 3637

To report any side effect(s):
• Saudi Arabia:
  – National Pharmacovigilance Center (NPC)
    • Fax: +966-1-205-7662
    • E-mail: npc.drug@sFDA.gov.sa
    • Website: www.sFDA.gov.sa/npc
• Other countries:
  • Please contact the relevant competent authority.

This is a Medicament

– Medicament is a product which affects your health and its consumption contrary to an instruction is dangerous for you.
– Follow strictly the doctor’s prescription, the method of use and the instructions of the Pharmacist who sold the medicament.
– The doctor and the pharmacist are the experts in medicines, their benefits and risks.
– Do not by yourself interrupt the period of treatment prescribed for you.
– Do not repeat the same prescription without consulting your doctor.
– Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists