Package leaflet: Information for the patient

Atrovent® 500 µg/2 mL Solution for inhalation
Nebuliser solution

Boehringer Ingelheim

Active substance: ipratropium bromide

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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 in
- chronic obstructive pulmonary disease (COPD)
- mild to moderate bronchial asthma in adults and children, as a supplement to $beta_2$-agonists in an acute asthma attack.

2. WHAT YOU NEED TO KNOW 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 allergic to ipratropium bromide, atropine or atropine derivatives (anticholinergic substances with a similar structure) or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using ATROVENT 500 µg/2 mL SOLUTION FOR INHALATION.

Care must be taken to ensure that the solution or inhalation mist does not get into the eyes.
ATROVENT 500 µg/2 mL SOLUTION FOR INHALATION should be used with caution in patients prone to narrow-angle glaucoma.
If this medicine accidentally gets into the eyes during use, mild and reversible eye complications may occur. In particular, patients with increased inner eye pressure (narrow-angle glaucoma) may suffer an acute glaucoma attack with the following typical symptoms: eye pain, blurred vision, cloudy vision, coloured halos around light sources or seeing false colours, 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 eye complications occur, an eye specialist should also be consulted.
If possible, a mouthpiece rather than a face mask should be used in such patients during inhalation, so that the medicine does not get into the eyes.

In patients with bladder-emptying problems (e.g. in patients with an enlarged prostate or narrowing of the bladder neck), ATROVENT 500 µg/2 mL SOLUTION FOR INHALATION should be used with caution.

Disturbances in gastrointestinal function and motility are more likely to occur in patients with cystic fibrosis.

If dyspnoea suddenly gets worse during inhalation (paradoxical bronchospasm), treatment must be stopped immediately and replaced by the doctor with a different therapy.

Immediate-type hypersensitivity reactions can occur after use of ATROVENT 500 µg/2 mL SOLUTION FOR INHALATION, e.g. rare cases of skin rash (exanthema), hives (urticaria), shock-like allergic reactions, including massive swelling (angioedema) of the tongue, lips and face and spasm of the bronchial muscles (bronchospasm).

Other medicines and ATROVENT 500 µg/2 mL SOLUTION FOR INHALATION

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.

Permanent use of ATROVENT 500 µg/2 mL SOLUTION FOR INHALATION with other active substances similar to ipratropium bromide (anticholinergic agents) has not been studied and is therefore not recommended.

Beta-adrenergic agents and xanthine preparations (e.g. theophylline) can increase its effect.

Other anticholinergic agents, such as preparations containing pirenzepine, can increase its effect and side effects.

The risk of an acute glaucoma attack in patients with narrow-angle glaucoma may be increased if ATROVENT 500 µg/2 mL SOLUTION FOR INHALATION and beta-agonists are used together.

Please note that this information can also apply to medicines recently used.

ATROVENT 500 µg/2 mL SOLUTION FOR INHALATION with food and drink

No restrictions apply.

Pregnancy, breast-feeding and fertility

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

There is no experience in humans with regard to use during pregnancy and breast-feeding.

Although no harmful effects on the foetus are known to date, ATROVENT 500 µg/2 mL SOLUTION FOR INHALATION should not be used during pregnancy, particularly during the first three months of pregnancy or while breast-feeding, unless your treating doctor thinks it necessary, after careful consideration of the benefits and risks.
In so doing, due consideration should be given to the risks of inadequate treatment.

Fertility
No clinical data on fertility are available for ipratropium bromide. Non-clinical studies with ipratropium bromide showed no adverse effect on fertility.

Driving and using machines

No studies on the ability to drive and use machines have been performed. During treatment with ATROVENT 500 µg/2 mL SOLUTION FOR INHALATION, 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. Caution should therefore be exercised when driving or using machines.

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

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Please follow the instructions for use, as ATROVENT 500 µg/2 mL SOLUTION FOR INHALATION may otherwise not work properly.
ATROVENT 500 µg/2 mL SOLUTION FOR INHALATION is intended for inhalation with a nebuliser only.

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

For acute treatment:
Adults and adolescents 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; the interval between individual inhalations must be decided by the doctor.

For long-term treatment:
Adults and adolescents over 12 years:
1 unit-dose vial 3-4 times a day.

Note:

A daily dose of more than 2 mg ipratropium bromide (4 unit-dose vials) should be reviewed regularly by the doctor.

Important note:
If, despite the prescribed therapy, there is no satisfactory improvement or if your condition gets worse, medical advice is required, so that the treatment can be reviewed and, if necessary, supplemented with other medicines (corticosteroids, beta-sympathomimetics, theophylline).
In the event of acute or rapidly worsening dyspnoea, medical help must be sought immediately.

How and when to use ATROVENT 500 µg/2 mL SOLUTION FOR INHALATION

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 must not be swallowed or injected.
ATROVENT 500 µg/2 mL SOLUTION FOR INHALATION can be used with standard nebuliser devices; if oxygen is administered, the ideal flow rate is 6–8 L/min.

If possible, this medicine 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 as directed by your treating doctor.

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

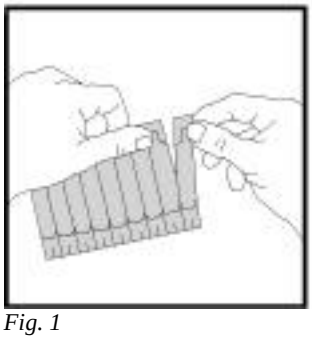
Fig. 1

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


Fig. 2

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

Fig. 3

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 get into 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 prone to glaucoma should take particular care to ensure that their eyes are protected during inhalation.

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

A fresh unit-dose vial should be used for each dose. If already broached, accidentally opened or damaged, unit-dose vials should be discarded.

ATROVENT 500 µg/2 mL SOLUTION FOR INHALATION is suitable for simultaneous 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 at the same time in the same nebuliser.

How long should you use ATROVENT 500 µg/2 mL SOLUTION FOR INHALATION?

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

Please talk to your doctor or pharmacist if you have the impression that the effect of ATROVENT 500 µg/2 mL SOLUTION FOR INHALATION is too strong or too weak.

What precautions must be followed?

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

If you have far exceeded the prescribed dose, you should seek medical help immediately. You might be at greater risk of experiencing side effects, such as dry mouth, problems with adjustment of the eyes to differing visual ranges and increased 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 you constantly use too low doses, there is a risk that your dyspnoea will increase.

If you stop using ATROVENT 500 µg/2 mL SOLUTION FOR INHALATION

Your illness may get worse if you interrupt treatment with ATROVENT 500 µg/2 mL SOLUTION FOR INHALATION or stop it too soon.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The commonest side effects (in 1-10% of patients) occurring with the use of ATROVENT are headache, dizziness, cough, throat irritation, dry mouth, altered taste, disturbances in gastrointestinal motility and nausea.

Certain uncommon side effects may occur (in 0.1-1% of patients). These include: immediate-type allergic reactions, hypersensitivity reactions, blurred vision, temporary pupil dilation, increased inner eye pressure, possibly with eye pain, cloudy vision and seeing rainbow colours (halos), increased blood flow to the conjunctiva, corneal swelling, glaucoma, increased palpitations, supraventricular heart rhythm disorders with increased heart rate, (inhalation-induced) bronchospasm (spasm of the bronchial muscles), spasm of the laryngeal muscles, throat swelling, dry throat, constipation, diarrhoea, abdominal pain, vomiting, inflammation of the mouth lining, swollen mouth, skin rash, itching, massive swelling of the tongue, lips and face, urinary retention.

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

As with all inhaled medicines, signs of local irritation in the throat region can occur in some patients.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

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

Keep this medicine out of the sight and reach of children.

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

Storage conditions

Store below 30°C, keep in the original carton.

Shelf life after opening

As the solution contains no preservative, the contents of the unit-dose vial must be inhaled immediately after opening; any remaining solution should be discarded.
If already broached, accidentally opened or damaged, unit-dose vials should be discarded.

Do not throw away any medicines via household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What ATROVENT 500 µg/2 mL SOLUTION FOR INHALATION contains

The active substance is: ipratropium bromide

2 mL solution (contents of one unit-dose vial) contains:
522 µg ipratropium bromide 1 H_2O (equivalent to 500 µg 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 nebuliser solution in a colourless, transparent, plastic unit-dose vial. 10 unit-dose vials are packed in a hermetically sealed, white aluminium pouch.

ATROVENT 500 µg/2 mL SOLUTION FOR INHALATION is available in the following pack sizes:

Pack containing 10, 20 or 50 unit dose vials of 2 ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Boehringer Ingelheim International GmbH
Binger Str. 173
D-55216 Ingelheim am Rhein
Germany

Manufacturer

Laboratoire Unither
Espace Industriel Nord
151 rue André Durouchez – CS 28028
80084 Amiens Cedex 2
France

This leaflet was last revised in August 2016.

Properties
ATROVENT 500 µg/2 mL SOLUTION FOR INHALATION is a medicine specifically for the prevention and treatment of dyspnoea in chronic obstructive pulmonary disease (COPD), mild to moderate bronchial asthma and as a supplement to beta$_2$-agonists in an acute asthma attack. Due to the site of action of the active substance in ATROVENT 500 µg/2 mL SOLUTION FOR INHALATION,

which is an anticholinergic agent, spasms of the bronchial muscles, triggered by the vagus nerve, are inhibited. This differentiates it from most other antispasmodic inhaled preparations.

ATROVENT 500 µg/2 mL SOLUTION FOR INHALATION dilates the airways. Regular use protects against constriction of the airways and spasms of the bronchial muscles.

Description of the pharmaceutical form
Clear, colourless solution

Other pharmaceutical forms

ATROVENT 250 µg/2 mL SOLUTION FOR INHALATION, nebuliser solution

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:
Boehringer Ingelheim
Middle East & North Africa
Tel: +971 (4) 423 0400
Fax: +971 (4) 423 3637

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