

ATROVENT[®] N METERED DOSE INHALER

Ipratropium Bromide (20mcg/puff)

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What *Atrovent* is used for

Atrovent is used as a bronchodilator for maintenance treatment of bronchospasm (tightening of the airways going into the lungs) associated with chronic obstructive pulmonary disease (progressive, obstructive lung disease characterized by chronically poor airflow), including chronic bronchitis (chronic inflammation of the lining of the airways), emphysema (damage to the air sacs (alveoli) in the lungs) and asthma.

How *Atrovent* works

The active substance of *Atrovent* - ipratropium bromide, an anticholinergic, works by relaxing the muscles around the airways.

Atrovent opens the airways with a very low dose of the active substance (1 pump = 21 µg ipratropium bromide). With regular preventative use, it protects against narrowing of the airways/bronchial muscle cramps. The bronchodilation following inhalation of *Atrovent* is primarily local and site specific to the lungs.

Before you use *Atrovent***- When you must not use it**

If you are hypersensitive (allergic) to ipratropium bromide, any other constituent of *Atrovent*, atropine or atropine derivatives (anticholinergic substances with a similar structure).

Pregnancy and lactation

Consult your doctor or pharmacist before taking or using any medications.

Although no teratogenic effects (harmful effects on fetus) are known, *Atrovent* should be used during pregnancy and while lactating, only if deemed necessary by the treating doctor after careful consideration of the risks versus the benefits.

- Before you start to use it

Please see below for information about when you should use *Atrovent* only in certain conditions and only with extreme caution. Please ask your doctor for more information. The same applies if the conditions below have applied to you in the past.

If the medication accidentally comes into contact with your eyes during use, you may experience eye complications. If you have narrow-angle glaucoma (increased fluid pressure in the eye) in particular, you may experience an acute glaucoma attack with the following typical symptoms: eye pain, blurred vision, foggy vision, halos around lights or changes in colour perception, eye redness and corneal swelling.

This can be treated with miotic eye drops. In the event of severe eye complications, you should consult an ophthalmologist.

Because the metered aerosol is delivered via a mouthpiece and manually controlled, the risk of spraying it into your eyes is low.

Atrovent should be used with caution if you have trouble emptying your bladder (such as enlarged prostates).

If you have cystic fibrosis (a genetic condition in which the lungs and digestive system become clogged with sticky mucus) you may be more susceptible to functional and mobility disorders of the gastrointestinal tract.

Special care must be taken when using *Atrovent*:

Be sure not to get the aerosol spray in your eyes (particularly for if you are prone to glaucoma); see "*Side effects.*"

- Taking other medicines

Please inform your doctor or pharmacist if you are taking or using or have recently taken or used other medicines, even if the other medicines do not require a prescription.

Beta 2 adrenergics and xanthine derivatives (such as theophylline) can increase the bronchodilatory effect (open the airways in the lungs).

How to use *Atrovent***- How much to use**

Always follow your doctor's exact instructions when using *Atrovent*. Please ask your doctor or pharmacist if you are not certain.

Please use as directed; otherwise, *Atrovent* may not have the desired effect. *Atrovent* is to be used for inhalation only.

Unless otherwise directed, the following doses are recommended in general for adults and children aged 6 and onwards: 2 metered doses (puffs) 4 times daily.

Use in children must be supervised by an adult.

If the number of required doses increases, it must be assumed that additional treatment will be necessary. Therefore, a total daily dose of 12 aerosol sprays is not to be exceeded.

Important note:

If no significant improvement is seen despite the prescribed treatment, or if your symptoms worsen, you must consult with your doctor to revise your treatment plan. In the event of acute or rapidly worsening shortness of breath, seek medical treatment immediately.

- When to use it

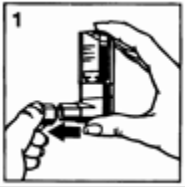
If possible, use while sitting or standing.

Correct handling of the metered aerosol is decisive for successful treatment.

Press the metered aerosol twice before first use.

Observe the following for each use:

1. Remove the protective cap (Fig. 1).



2. Exhale deeply.
3. Put the metered aerosol in your mouth and close your lips tightly around the mouthpiece. The arrow and the base of the container should be pointing upwards.



4. Inhale deeply while pressing firmly on the bottom of the canister to release an aerosol spray. Hold your breath for a few seconds, then remove the mouthpiece from your mouth and exhale slowly. The same action should be repeated for a second inhalation.

5. Replace the protective cap after use.

Be sure that no spray gets into your eyes.

- How long to use it

Your doctor will determine the duration of treatment based on the current status of your illness and severity of side effects. Under no circumstances should you change or discontinue treatment on your own.

Please consult your doctor or pharmacist if you feel that the effect of Atrovent is too strong or too weak.

- If you forget to use it

Do not take a double dose if you have forgotten the previous dose. Inhale the next dose at the regular time. If you miss too many doses, there is the risk that your shortness of breath will worsen. The procedure is the same as for impending shortness of breath.

- If you use too much (overdose)

A total daily dosage of more than 12 aerosol pumps does not generally offer any additional treatment benefit. Seek medical treatment immediately if you have used significantly more than the prescribed dose. You may have a higher risk of side effects such as dry mouth, trouble adjusting your eyes to different distances and a rapid heartbeat.

While you are using it

- Things you must do

Clean your metered aerosol at least once per week.

It is important to keep the mouthpiece of your metered aerosol clean in order to ensure that the medication does not form a residue and block the spray.

To clean it, first remove the protective cap and remove the canister from the mouthpiece. Run warm water over the mouthpiece until it is free of debris.



Shake the mouthpiece after cleaning and let it air dry. When the mouthpiece is dry, place the canister inside it again 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 developed exclusively for use with the Atrovent. Do not use the mouthpiece with other aerosols. Use the Atrovent only with the mouthpiece that was provided with it.

- Things you must not do

Your shortness of breath may increase if you interrupt treatment or discontinue it prematurely. You should therefore not interrupt or discontinue treatment with Atrovent without consulting your treating doctor.

Do not give Atrovent to anyone else, even if they have the same symptoms or condition as you.

The container is under pressure and should by no account be opened by force or exposed to temperatures above 50°C.

If you have any other questions about using this medication, contact your doctor or pharmacist.

- Things to be careful of

Warnings:

If your shortness of breath becomes acutely worse (paradoxical bronchospasm) during inhalation, you must stop treatment immediately and have your doctor review your treatment plan.

Immediate hypersensitivity reactions can occur after using Atrovent, such as rare cases of skin rash, itching (urticaria), allergic shock reactions and massive swelling (angioedema) of the tongue, lips and face, and muscle cramps of the bronchial airways (bronchospasm)

Ability to drive and operate machines

No studies have been conducted regarding effects on ability to drive or to operate machinery. During treatment of Atrovent, adverse effects such as dizziness, problems adjusting the eyes to different distances (accommodation disorders), temporary dilation of the pupils (mydriasis) and blurred vision may occur. Therefore, you should use caution when driving or operating machinery. If you experience the above side effects, you should not drive or work with machinery.

Side effects

As with all medications, Atrovent can have side effects that will not necessarily occur in everyone.

The most frequent side effects of Atrovent are headache, dry mouth, dizziness, coughing, irritation of the throat, dry mouth, motility disorders of the gastrointestinal tract (including constipation, diarrhea and vomiting) and nausea.

Please inform your doctor or pharmacist if you are significantly affected by one of the above side effects or if you detect side effects that are not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

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Storage and disposal of Atrovent

- Storage

Keep out of the reach and sight of children.

Store below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

- What it looks like

Clear, colourless liquid, free from suspended particles

- Ingredients

- Active ingredient

Ipratropium bromide

- Inactive ingredients

Citric acid anhydrous, purified water, ethanol anhydrous, nitrogen (inert gas), HFA [hydrofluoralkane] 134a (propellant)

- MAL number:

MAL20033948AZ

Manufacturer

Boehringer Ingelheim Pharma GmbH & Co. KG

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Product Registration Holder

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