

Package leaflet: Information for the user

Atrovent 20 microgram/dose, aerosol, solution ipratropium bromide

Read the entire 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.

Do you have any questions? Please contact your doctor or pharmacist.

Do not pass this medicine on to others, as it has been prescribed only for you. It may be harmful to others, even if their symptoms are the same as yours. Do they have the same symptoms as you.

Do you experience any of the side effects listed in section 4? Or do you experience a side effect not mentioned in this leaflet? Then contact doctor or pharmacist. Contents of this leaflet:

What is Atrovent

1. What is Atrovent When should you not use this medicine or be extra careful with it?
2. When should you not use this medicine or be extra careful with it?
3. How do you use this medicine?
4. Possible side effects
5. How do you store this medicine?
6. Contents of the package and other information

1. What is Atrovent 20 microgram/dose, aerosol, solution and what is it used for?

Atrovent belongs to the category of bronchodilators.

One inhalation contains 21 micrograms of ipratropium bromide corresponding to 20 micrograms of anhydrous ipratropium bromide.

Atrovent belongs to the group of medicines called 'anticholinergic bronchodilators'. It works as follows.

After inhalation, the active substance ipratropium bromide helps to relax the muscles around the airways. This allows the airways to widen and makes it easier to breathe.

Atrovent can be used to relieve narrowing of the airways, such as in (chronic) bronchitis, bronchitis with emphysema or asthma.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6. You are allergic to substances similar to ipratropium bromide (atropine-like substances).

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine.

If after using this medicine you experience an abnormal cramp of the muscles around the windpipe (paradoxical bronchospasm). This can be life-threatening, you must stop using this medicine immediately. Also contact your doctor for another method of treating your symptoms.

If you have increased eye pressure (glaucoma). Eye pain or blurred vision, seeing colored rings or images in combination with red eyes due to swelling of the eye can be signs of increased eye pressure (glaucoma). If a combination of these symptoms occurs, medical advice is immediately necessary.

Do not spray Atrovent in or around the eyes. If this happens, rinse the eyes immediately with cold tap water for a few minutes. If some of the product accidentally gets into the eye during spraying, pupil dilation (mydriasis) and blurred vision may occur, which can last for several hours. If this is accompanied by redness of the eye, pain, or an unpleasant feeling in the eye, you should consult a doctor immediately.

If you have a prostate disorder (prostatic hyperplasia) or a blockage of the urinary tract.

If you have cystic fibrosis. When using anticholinergics (ipratropium bromide), you may be more sensitive to gastrointestinal complaints.

Are you using any other medicines?

Are you using any other medicines besides Atrovent 20 micrograms/dose, aerosol, solution, have you done so recently, or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist. Atrovent and other medicines can influence each other's effects. Medicines where this is the case:

Medicines from certain

- Medicines from certain pregnancy and breastfeeding

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Contact your doctor or pharmacist before using this medicine.

No adverse effects are known to date regarding use during pregnancy. Ask your doctor or pharmacist for advice before using any medicine.

There is insufficient data on the use during breastfeeding to assess potential harm.

Driving and using machines

There is no data available on the effect of Atrovent on driving ability. When driving vehicles and operating machines, consider the possibility of side effects such as dizziness and eye problems like pupil dilation, difficulty focusing the eye lens (accommodation disorder), and blurred vision. Be cautious until you know how you react to Atrovent.

Atrovent aerosol contains alcohol

This medicine contains 8 mg of alcohol (ethanol) per inhalation. The amount per inhalation in this medicine is equivalent to less than 1 ml of beer or 1 ml of wine.

There is a small amount of alcohol in this medicine. It is so little that you will not notice it.

3. How do you use this medicine?

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

The dosage is determined individually, and the patient should be under medical supervision during treatment.

The recommended dosage is, unless otherwise prescribed:

Adults and children from 6 years: 3 to 4 times a day two inhalations. Generally, no more than 12 inhalations per day should be used.

The effect occurs within a few minutes and lasts for a maximum of 6 hours. Use Atrovent every day, always at the same times of the day. This gives the best effect. The fixed times also help you remember when to inhale.

Atrovent is used for the treatment of long-term respiratory conditions. Therefore, Atrovent must be used for an extended period.

For the success of the treatment, it is important that you use the aerosol correctly.

Before using the canister for the first time, you should press the reservoir twice. If you have not used the canister for more than three days, you should press the reservoir once before use.

The following rules must be followed before each use:

Method of administration:

1. Remove the protective cap from the mouthpiece ..
2. Exhale as deeply as possible.
3. Exhale as deeply as possible.
4. Now inhale as deeply as possible through the mouth and simultaneously press the canister firmly once. Hold your breath for a few seconds, remove the mouthpiece, and exhale. Repeat this procedure from point three if a second inhalation is prescribed.
5. Inhale as deeply as possible through the mouth and simultaneously press the canister firmly once. Hold your breath for a few seconds, remove the mouthpiece, and exhale.
6. Repeat this procedure from point three, if a second inhalation is prescribed.
7. Place the protective cap back on the mouthpiece.

N.B. When using Atrovent for the first time, if you find it difficult, you can try it in front of a mirror first.

Because the canister is not transparent, it is not possible to see when it is empty. The canister contains 200 inhalations. After 200 inhalations, it may seem like there is still a little liquid in the canister. You should then replace the inhaler with a new one. This ensures that you receive the correct amount of medication with each puff. It is very important to keep the mouthpiece clean. If you do not clean it regularly, the mouthpiece can become blocked and stop working.

Some patients mistakenly think the canister is empty. Therefore, clean the mouthpiece at least once a week.

To clean the mouthpiece, first remove the protective cap and the canister from the mouthpiece. Then rinse the mouthpiece with warm water. Do this until you no longer see any medication and/or dirt (figure 2).

Shake the mouthpiece and let it air dry; do not use a heating element (e.g., hairdryer) for drying. Place the canister and protective cap back when the mouthpiece is dry. Now check the metal canister. Even with normal use, the holes in the outlet tube can become blocked. With a fine needle, the tube can be easily opened.

N.B. The mouthpiece is specially designed for use with Atrovent to ensure that you always receive the correct amount of medication. Therefore, the mouthpiece should not be used with other dose aerosols. You should also not use Atrovent with another mouthpiece. If you notice that Atrovent is too strong or not strong enough, consult your doctor or pharmacist.

In case of sudden or rapidly worsening breathing difficulties be targeted.

N.B. The mouthpiece is specially designed for use with Atrovent to ensure that you always receive the correct amount of the medication. Therefore, the mouthpiece should not be used on other dose aerosols. You must not use Atrovent with another mouthpiece.

If you notice that Atrovent is too strong or not effective enough, consult your doctor or pharmacist.

In case of sudden or rapidly worsening breathing difficulties you should consult a doctor immediately.

Have you used too much of this medicine?

No specific symptoms have been observed after an overdose. If you experience complaints after an overdose, you can consult your doctor.

Did you forget to use this medicine?

If you have forgotten an inhalation, you can still do it. However, if it is almost time for the next inhalation, you can skip the missed inhalation and continue according to your doctor's dosing instructions. Do not take a double dose to make up for a forgotten dose.

If you stop using this medicine

Do not stop Atrovent on your own initiative. Always consult your doctor if you are considering stopping. If you stop in consultation with your doctor, the complaints you had before treatment with Atrovent may return.

4. Possible side effects

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

Side effects may occur:

frequently (occur in less than 1 in 10 patients)

sometimes (occur in less than 1 in 100 patients)

rarely (occur in less than 1 in 1000 patients)

The side effects are arranged by organ.

Immune system

Sometimes: Hypersensitivity and severe hypersensitivity reaction (anaphylaxis).

Nervous system

Often: Headache and dizziness.

Eye

Sometimes: Blurred vision, increased intraocular pressure (glaucoma) (see also: when should you be extra careful with this medicine), eye pain, dilation of the pupils (mydriasis), seeing colored rings (visual halos), bloodshot eyes (conjunctival hyperemia) and fluid accumulation in the cornea (corneal edema).

Rarely: Difficulty focusing the eye lens (accommodation disorder).

Heart

Sometimes: Palpitations (at higher dosages), regular but very rapid contraction of the heart (atrial fibrillation) and arrhythmias.

Rarely: Increased heart rate.

Respiratory system and thoracic disorders

Common: Cough and throat irritation.

Rare: Narrowing of the airways as a result of inhalation (bronchospasm), spasm of the vocal cords (laryngospasm), swelling of the throat and dry throat.

Gastrointestinal system

Common: Dry mouth, gastrointestinal disorders, and nausea.

Sometimes: Diarrhea, constipation, vomiting, inflammation of the oral mucosa (stomatitis), fluid retention in the mouth, and taste changes.

Skin disorders

Sometimes: Itching (pruritus), rash, sudden fluid retention in the skin and mucous membranes (e.g., throat or tongue), breathing difficulty breathing and/or itching and skin rash (angioedema).

Rare: Skin rash with severe itching and formation of welts (urticaria).

If you experience the side effect of acute localized swelling of the tongue, lips, and face, you should immediately consult a doctor.

Kidney and urinary disorders

Sometimes: Retention of urine. In case of a urinary tract obstruction, caution is advised (see also: when should you be extra careful with this medicine).

Reporting side effects

Do you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the

Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How do you store this medicine?

Keep out of the sight and reach of children.

Store below 30°C.

Protect from direct sunlight, heat, and freezing.

The aerosol can is under pressure and must not be opened or damaged by force. Opening it is dangerous and also makes the contents immediately unusable.

The aerosol can must not be exposed to temperatures above 50°C (e.g., on central heating or a stove).

Do not use this medicine after the expiration date. It is found on the box after 'do not use after' or 'EXP'. It includes a month and a year. The last day of that month is the expiration date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

6. Contents of the package and other information

What substances are in this medicine?

The active substance in this medicine is ipratropium bromide.

The other substances (excipients) in this medicine are citric acid (E 330), purified water, absolute alcohol, and propellant (HFA 134a).

What does Atrovent 20 micrograms/dose, aerosol, solution look like and how much is in a package?

A package of Atrovent aerosol contains an aerosol can with a mouthpiece with 10 ml solution for inhalation, corresponding to 200 inhalations.

Marketing authorization holder and manufacturer

Marketing authorization holder

Boehringer Ingelheim bv

Basisweg 10

1043 AP Amsterdam

Tel.: 0800-2255889

Manufacturer

Boehringer Ingelheim Pharma GmbH & Co. KG

Binger Straße 173

D-55216 Ingelheim am Rhein

Germany

Informational translation – not the official patient leaflet

Registered under RVG 26834

This leaflet was last approved in February 2022

Transtoyou

*This translation is provided by Transtoyou for informational purposes only.
The official patient information leaflet in the language of the country of delivery is always included
with the medication.*

