

Package leaflet: Information for the patient

Ipravent 20 micrograms per actuation pressurised inhalation, solution

(Ipratropium bromide as the monohydrate)

The name of this medicine is 'Ipravent 20 micrograms per actuation pressurised inhalation, solution' which will be referred to as 'Ipravent Inhaler' throughout this leaflet.

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ipravent Inhaler is and what it is used for
2. What you need to know before you use Ipravent Inhaler
3. How to use Ipravent Inhaler
4. Possible side effects
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1. What Ipravent Inhaler is and what it is used for

Ipravent Inhaler contains a medicine called ipratropium bromide. This belongs to a group of medicines called bronchodilators.

It is used to make breathing easier for adults with chronic asthma or 'chronic obstructive pulmonary disease' (COPD).

Ipravent Inhaler works by opening up airways.

2. What you need to know before you use Ipravent Inhaler

Do not use Ipravent Inhaler:

- If you are allergic to ipratropium bromide or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to similar medicines which contain atropine or medicines like atropine, hyoscyamine and scopolamine.

Do not use if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Ipravent Inhaler.

Warnings and precautions

Talk to your doctor or pharmacist before using Ipravent Inhaler:

- If you have glaucoma with narrow chamber angle (a disorder in which pressure within eye increases), or have been told that you may develop it.
- If you have problems passing water (urine).
- If you are a man who has prostate problems.
- If you have cystic fibrosis (a genetic disorder of digestive system which affects food break down and absorption).

- If you develop acute or rapidly deteriorating dyspnea (difficulty breathing).

If you are not sure if any of these apply to you, talk to your doctor or pharmacist before using Ipravent Inhaler.

Ipravent Inhaler may rarely cause allergic reactions right after the use. They may appear as hives or swelling of the upper airway.

Stop taking Ipravent Inhaler and tell your doctor if you experience any of the following symptoms (angioedema):

- swelling of the face, tongue or throat
- difficulty in swallowing
- hives and difficulty in breathing

Always contact your doctor if breathing difficulties continue or worsen despite treatment. In acute deterioration of lung function contact your doctor immediately.

Ipravent Inhaler can cause dry mouth, which in long term treatment can lead to dental and oral mucosal changes. The teeth should be thoroughly cleaned with fluoride toothpaste twice a day.

Children and adolescents

This medicine is not intended for the use in children and adolescents.

Other medicines and Ipravent Inhaler

Tell your doctor or pharmacist if you are taking, have recently taken or might use any other medicines. This includes herbal medicines. This is because Ipravent inhaler can affect the way some other medicines work. Also some other medicines can affect the way Ipravent inhaler works.

In particular, tell your doctor or pharmacist if you are taking/have taken any of the following medicines:

- Any other inhalers to help you to breathe more easily such as the reliever inhaler salbutamol.
- Medicines called 'xanthines' to help your breathing such as theophylline and aminophylline.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using Ipravent Inhaler.

Pregnancy, breastfeeding and fertility

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 taking this medicine.

As a precautionary measure, it is preferable to avoid the use of Ipravent Inhaler during pregnancy. There is no data for its use in pregnancy. You should consult your physician before you use Ipravent Inhaler during pregnancy.

It is not known whether Ipravent Inhaler is excreted in human milk. You should consult your doctor before you use Ipravent during lactation.

Driving and using machines

You may feel dizzy, or have difficulty focusing, visual disturbances or blurred vision while using Ipravent Inhaler. If this happens do not drive or use any tools or machines. You should assess whether you are fit to drive or perform tasks that require alertness.

Ipravent Inhaler contains ethanol (alcohol)

This medicine contains 8.4 mg of alcohol (ethanol) in each spray. The amount in each dose of this medicine is equivalent to less than 4.3 ml beer or 1.72 ml wine.

The small amount of alcohol in this medicine will not have any noticeable effects.

3. How to use Ipravent Inhaler

Always use Ipravent Inhaler exactly as your doctor has told you. Check with your doctor if you are not sure.

Follow these instructions to get the best results. If anything is unclear after reading this leaflet, ask your doctor or pharmacist.

The recommended dose is

Adults (including the elderly)

- 1-2 puffs to be inhaled four times daily.
- Maximum 12 puffs per day.

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Do not take more inhalations than your doctor prescribed. Check with your doctor, pharmacist or nurse if you are not sure.

Testing your Inhaler

When you use the inhaler for the first time you should test if it works properly. Also do this if you have not used the inhaler for 3 or more days.

1. Remove the mouthpiece cover by gently pressing the sides with your thumb and index finger.
2. Point the mouthpiece away from you and press the canister twice (once at a time) to release two puffs into the air.

How to use your Inhaler

It is important to start to breathe as slowly as possible just before using your inhaler.

1. You should either stand up or sit upright when using your inhaler
2. Remove the mouthpiece cover. Check inside and outside to make sure that the mouthpiece is clean and free of objects (figure A).



3. Hold the inhaler upright with your thumb on the base, below the mouthpiece. Breathe out for as long as is comfortable (figure B). Do not breathe in again yet.



4. Place the mouthpiece in your mouth between your teeth. Close your lips around it. Do not bite (figure C).



5. Breathe in through your mouth. Just after starting to breathe in, press down on the top of the canister to release a puff of medicine. Do this while still breathing in steadily and deeply (figure C).

6. Hold your breath, take the inhaler from the mouth and your finger from top of the inhaler. Continue holding your breath for a few seconds, or as long as is comfortable (figure D).



7. If your doctor has told you to take two puffs, wait about a minute before you take another puff by repeating steps 3 to 7.
8. After using your inhaler always replace the mouthpiece cover straight away to keep out dust. Replace the cover by firmly pushing and clicking into position.

The mouthpiece has been designed specially for use with this medicine only. Do not use any other mouthpiece with the medicine and do not use the mouthpiece provided here with any other medicine.

Practice in front of a mirror the first few times. If you see “mist” coming from the top of your inhaler or the sides of your mouth you should start again.

People with weak hands may find it easier to hold the inhaler with both hands. Put the two forefingers on top of the inhaler and both thumbs on the bottom below the mouthpiece. Your doctor, nurse or pharmacist will be able to advise you.

The inhaler can be used with a device called Aerochamber Plus spacer. This may be useful for people who find it difficult to synchronise breathing in and inhaler actuation.

Please talk to your doctor if you have difficulties to use the Ipravent inhaler.

When using your Ipravent Inhaler take care not to let any of the spray enter your eyes.

If ipravent accidentally get into your eyes, you should rinse your eyes with running water. If any of the spray accidentally gets into your eyes you may get painful, stinging or red eyes, dilated pupils, blurred vision, see colours or lights. If this happens, talk to your doctor for advice. If you get problems with your eyes at any other time, talk to your doctor for advice. You may be developing glaucoma, which will need treatment straight away.

Cleaning your Inhaler

It is important to clean your inhaler regularly. Otherwise it may not work properly.

- Remove the canister and cap.
- Wash and clean the white mouthpiece in warm soapy water.
- Rinse in warm water and allow to air dry without using any heating system.
- Make sure the small hole in the mouthpiece is washed through thoroughly.
- Once the mouthpiece is dry, replace the canister and the cap.

Do not put the metal canister into water.

Do not use more than your doctor has told you

See your doctor straight away if:

- You feel that your inhaler is not working as well as usual.
- You need to use the inhaler more than your doctor has recommended.

Your doctor may need to check how well your medicine is working. In some cases your doctor may need to change your medicine.

Make sure you do not run out of Ipravent Inhaler

The inhaler has been designed to deliver 200 puffs of your medicine. However, it is not possible to tell when the inhaler is empty and when the 200 puffs have been used. There may still be a small amount of fluid left over in the container. Please make sure that your inhaler is replaced after you have taken

200 puffs (usually after 3-4 weeks of regular use) so that you can be certain that you are getting the right amount of your medicine in each puff.

If you use more Ipravent Inhaler than you should

If you use more of this inhaler than you should, talk to a doctor or go to a hospital straight away. Take all your inhalers and any other medicines you are taking (in their packaging if possible) with you. If you take too much or too many puffs you may get a dry mouth, a rapid heart rate, enlarged pupil, difficulty to pass urine, headache, constipation and dizziness.

If you forget to use Ipravent Inhaler

- If you forget a dose, inhale it as soon as you remember it.
- However, if it is time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose

If you have any further questions, ask your doctor or pharmacist.

If you stop using Ipravent Inhaler

Do not stop using Ipravent Inhaler unless your doctor tells you to. 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.

Seek immediate medical advice if you notice any of the following serious side effects – you may need urgent medical treatment:

- If after using Ipravent Inhaler you are wheezy or have other difficulties in breathing, do not use any more (unless you have been told to by your doctor) (may affect up to 1 in 100 people)
- Swelling of your mouth and face, sudden difficulties in breathing, reduction of your blood pressure or tightening of your throat. This may be signs of allergic reactions or angioedema (may affect up to 1 in 100 people).
- If you get problems with your eyes. You may be developing glaucoma, which will need treatment straight away (may affect up to 1 in 100 people). If any of the spray accidentally gets into your eyes you may get painful, stinging or red eyes, dilated pupils, blurred vision, see colors or lights. If Ipravent Inhaler accidentally get into your eyes, you should rinse your eyes with running water and talk to your doctor for advice.

The side effects described below have been experienced by people taking Ipravent Inhaler and they are listed as either common, uncommon, rare or not known frequency.

Common (may affect up to 1 in 10 people)

- Headache, dizziness
- Dry mouth, feeling sick (nausea), stomach upset or discomfort, disturbed bowel function.
- Cough and throat irritation when you have just used Ipravent Inhaler

Uncommon (may affect up to 1 in 100 people)

- Itching, skin rash.
- Unexpected tightness of the chest, swelling of the throat, dry throat.
- Diarrhoea, constipation or being sick.
- Mouth or lip sores.
- Problems passing water (urine), especially if you already have problems passing urine.

Rare (may affect up to 1 in 1,000 people)

- Difficulties to set the vision at different distances

- increased heart rate
- atrial fibrillation
- Nettle rash (urticaria)

Not known (frequency cannot be estimated from the available data)

- Changes in taste
- Shortness of breath
- Stuffy nose
- Nasal dryness

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

[To be completed nationally]

5. **How to store Ipravent Inhaler**

Keep this medicine out of sight and reach of children

Do not use Ipravent Inhaler after the expiry date which is stated on the carton and canister label after EXP. The expiry date refers to the last day of that month.

Protect from direct sunlight, heat and frost.

If the Inhaler has been exposed to low temperatures, the patient should take the metal canister out of the plastic case and warm it in their hands for a minimum of two minutes.

The canister contains a pressurised liquid. Do not expose to temperatures higher than 50°C. Do not try to open, puncture or burn the canister even when apparently empty.

Do not throw away any medicines via waste water or 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 Ipravent Inhaler contains

- The active substance is ipratropium bromide.
One actuation contains 20 micrograms ipratropium bromide (as the monohydrate). Each canister contains 200 actuations.
- The other ingredients are propellant HFC-134a (Norflurane), citric acid anhydrous, ethanol anhydrous and purified water.
- This medicine contains fluorinated greenhouse gases.
- Each inhaler contains 12.3 g of HFC-134a (Norflurane) corresponding to 0.018 tonne CO₂ equivalent (global warming potential GWP =1430).

What Ipravent Inhaler looks like and contents of pack.

Ipravent Inhaler is a colourless solution, filled in an aluminum container fitted with a suitable metering valve and a plastic actuator.

The inner packaging is a 19 ml silver anodised aluminium container fitted with a suitable 50 microliter metering valve and the plastic actuator. The valve contains a thermoplastic 2-part core, cup (body), metering chamber, 2 elastomeric seats and gasket, a metallic ferrule and a spring. The plastic actuator body & cap are made up of polypropylene.

Each container is filled to deliver 200 metered doses.

Pack sizes

For DE, SE and PL.

Single pack

Each single pack contain a canister with 200 actuations (puffs).

For DE and PL

Multipack

400 actuations (2 x 200). Bundle pack of 2 single packs.

600 actuations (3 x 200). Bundle pack of 3 single packs.

For DE

Hospital pack

2000 actuations (10 x 200). Bundle pack of 10 single packs. Component of a hospital pack, can't be sold separately.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

<{To be completed nationally}>

Manufacturer

Cipla Europe NV, De Keyserlei 60C, Bus-1301, 2018 Antwerp, Belgium

Glenmark Pharmaceuticals s.r.o., Fibíchova 143, 566 17 Vysoké Mýto, Czech Republic

This medicinal product is authorised in the Member States of the EEA under the following names:

<{Name of the Member State}> <{Name of the medicinal product}>

<{Name of the Member State}> <{Name of the medicinal product}>

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