

New Zealand Consumer Medicine Information

COMBIVENT[®]

Metered Aerosol

Ipratropium bromide and Salbutamol sulphate

What is in this leaflet

This leaflet answers some common questions about COMBIVENT metered aerosol. It does not contain all available information. Nor does it take the place of talking to your doctor or pharmacist. Keep this information with your metered aerosol. You may need to read it again later.

To find out more about COMBIVENT

You should ask your doctor or pharmacist if you have any questions about your medicine or if you have any trouble before, during or after using COMBIVENT.

What COMBIVENT is used for

COMBIVENT is used to make breathing easier for people with obstructive airway diseases, such as COPD, bronchitis, emphysema and related conditions. COMBIVENT improves breathing by relaxing the breathing tubes or air passages that carry air to and from the lungs. It begins to act quickly (15 minutes) after use and usually lasts for 4-6 hours.

COMBIVENT contains two active ingredients: ipratropium bromide and salbutamol sulphate. These medications act in different ways. When used in combination, the improvement in breathing is better than when each medicine is used alone.

Before you use COMBIVENT

When you must not use COMBIVENT

Only use COMBIVENT if it has been prescribed for you by a doctor. Never give it to someone else even if their symptoms seem to be the same as yours.

Do not use COMBIVENT if you are allergic to atropine or its derivatives or to any of the ingredients. Do not use COMBIVENT if you are allergic to soya lecithin or related food products such as soya bean and peanuts. These ingredients are listed in full at the end of this leaflet (see ingredients).

If you are uncertain as to whether you have these allergies you should raise your concerns with your doctor.

Do not use COMBIVENT if you have certain heart conditions known as hypertrophic obstructive cardiomyopathy (heart muscle disease) or tachyarrhythmia (fast heart rate).

You should never use COMBIVENT after the EXPIRY DATE on the canister or carton.

Before you start to use COMBIVENT

It is essential that your doctor knows your medical history before prescribing COMBIVENT. Before using COMBIVENT, you must tell your doctor if you have, or have had, any of the following conditions:

- an eye problem called "glaucoma"
- a disorder of sugar control (diabetes mellitus)
- a heart attack
- a severe heart or blood vessel disorder
- an overactive thyroid gland (hyperthyroidism)
- a tumour which results in raised blood pressure (phaeochromocytoma)
- problems with passing urine
- low blood potassium levels
- cystic fibrosis.

If you are uncertain as to whether you have, or have had, any of these conditions you should raise those concerns with your doctor.

Before taking COMBIVENT you must tell your doctor if you are taking any other medicines, obtained with or without a doctor's prescription. In particular you must tell your doctor if you are taking:

- theophylline containing medicines
- corticosteroids
- diuretics
- digoxin
- beta-blockers
- monoamine oxidase inhibitors (MAOIs)
- tricyclic antidepressants
- anaesthetics.

Pregnancy

Ask for your doctor's advice if you are pregnant, or likely to become pregnant during your course of medication. Special care is recommended during pregnancy, particularly in the first three months and caution is advised before child birth.

Breastfeeding

Ask for your doctor's advice if you are breastfeeding or likely to breastfeed during the course of your medication. Special care is recommended if you are breastfeeding as it is possible that the active ingredients may be distributed into breast milk.

Children

COMBIVENT is not recommended for use in children.

Using COMBIVENT

How to use COMBIVENT

Shake the metered aerosol before using. This will mix the medicine evenly so that a correct dose is delivered. Each puff must be inhaled through the mouth properly for COMBIVENT to work. At the end of this leaflet you will find instructions on how to correctly inhale COMBIVENT.

If you have any problems with inhaling COMBIVENT ask your doctor or pharmacist for advice.

Never spray COMBIVENT in or around your eyes. Should this occur, immediately flush your eyes with cold tap water for several minutes.

How much COMBIVENT to use

The recommended dose for adults is 2 puffs four times daily (at regular intervals), up to a maximum of 12 puffs in 24 hours. If your doctor has prescribed a different dose, you should ask for further information from your doctor or pharmacist.

If you forget to take a dose

It is important to use COMBIVENT as directed. If you miss a dose, take it as soon as you remember. However, if you remember when it is almost time for your next dose, take only your usual dose at that time. Do not take a double dose to make up for the dose that you missed.

If you use too much COMBIVENT

Seek medical advice if you have used more than the recommended or prescribed dose of COMBIVENT and you experience signs of overdose as listed below. Advice can be provided by a doctor, pharmacist or Poisons Information Centre (telephone 0800 POISON or 0800 764766).

Signs of overdose may include fast or irregular heart beat, shaky feeling, nausea, chest pain, flushing, dryness of the mouth and blurred vision.

While you are using COMBIVENT

It is very important to follow the Directions for Use carefully and avoid contact of the aerosol with the eyes. Contact your doctor immediately if you experience eye pain or discomfort, or any disturbances with your sight (blurred vision, visual halos or coloured images) during or after using COMBIVENT. This is because there have been isolated reports of narrow-angle glaucoma with the use of COMBIVENT.

If your breathing becomes more difficult while you are using COMBIVENT, tell your doctor immediately.

If you are a smoker, your doctor or pharmacist can advise you on the steps to take to quit smoking.

Tell your doctor or pharmacist if you begin taking any other medicine while you are using COMBIVENT. This applies to all medicines obtained with or without a doctor's prescription.

Side effects

You should be aware that all prescription medicines carry some risks and that all possible risks may not be known at this stage despite thorough testing. Your doctor has weighed the risks of you taking COMBIVENT against the benefits they expect it will have for you. Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of taking this medicine. The following side effects of COMBIVENT are sometimes reported:

- dryness of the mouth

- headache
- cough.

Less frequently reported side effects of COMBIVENT include the following:

- fast or irregular heartbeat
- nausea
- nervousness
- tremors
- urinary retention (difficulty passing urine)
- dizziness
- narrow-angle glaucoma (a condition affecting the eyes). The following symptoms may be associated with narrow-angle glaucoma: red eyes, eye pain or discomfort, sight disturbances (blurred vision, visual halos or coloured images).

Direct contact of the spray with the eyes may temporarily affect the ability of the eyes to focus. However, in some patients this may cause the more serious eye problem of narrow-angle glaucoma mentioned above, to develop or worsen. Therefore it is very important to follow the Directions for Use carefully and avoid contact with the eyes.

Rare side effects include:

- restlessness
- muscle weakness and cramps
- worsening of breathing problems (induced by the inhalation process)
- throat irritation
- 'warm feeling'
- vomiting
- change in bowel movements (eg constipation, diarrhoea)
- allergic reactions: most of the cases of allergic reactions have involved patients who have had a history of allergy to other drugs and/or foods. Allergic reactions may include skin rash, swelling of the tongue, lips and face, and difficulty breathing. Life threatening allergic reactions have been reported.

In a few people, the medicine in COMBIVENT may decrease blood potassium levels. Your doctor may do tests to check this.

Tell your doctor as soon as possible if you experience any side effects during or after using COMBIVENT, so that these may be properly treated.

Not all of these side effects have been reported with COMBIVENT but have been seen with similar medicines. In addition, unexpected effects, not listed above, can occur with any medicine. You should tell your doctor or pharmacist if you notice anything unusual, during or after using COMBIVENT.

After using COMBIVENT

Care and cleaning

Follow the instructions under the heading Care and cleaning in the Directions for use at the end of this leaflet. Your aerosol may not work properly if it gets dirty and is not cleaned.

Storage

COMBIVENT should be kept in a cool, dry place where the temperature stays below 30°C. For example, do not leave it in the car on hot days. The canister must never be

forced open, punctured or thrown into a fire even when it seems empty. If this occurs, the canister may explode.

Keep your COMBIVENT metered aerosol where children cannot reach them.

Disposal

If your doctor tells you that you will not be needing COMBIVENT anymore, the unused medicine should be returned to your pharmacist so that it can be disposed of safely.

Product Description

What COMBIVENT is

COMBIVENT is the brand name of your medicine. It is a hand-operated metered aerosol that delivers a fixed dose of medication from the canister.

Canisters containing 200 puffs are available.

Ingredients

Each puff of COMBIVENT contains ipratropium bromide 21 micrograms [equivalent to ipratropium bromide (anhydrous) 20 micrograms] and salbutamol sulphate 120 micrograms [equivalent to salbutamol 100 micrograms], which are delivered to your lungs by a mixture of propellant gases.

These gases (commonly known as CFCs) are:

- Trichloromonofluoromethane
- Dichlorodifluoromethane
- Dichlorotetrafluoroethane

COMBIVENT also contains soya lecithin as an emulsifier (mixing agent).

Distributor

COMBIVENT is supplied in New Zealand by:
BOEHRINGER INGELHEIM (N.Z.) LIMITED
PO Box 76-216
Manukau City
Auckland
Ph 0800 802461

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COMBIVENT[®]
Metered Aerosol
Ipratropium bromide and Salbutamol sulfate

Directions for Use

When using the aerosol for the first time it should be shaken and the valve depressed once or twice to prime the metering valve before initial use.

The correct operation of the metered aerosol apparatus is essential for successful therapy.

- 1) Remove the protective cap.
- 2) Shake the metered aerosol well before each use. (See Fig 1)

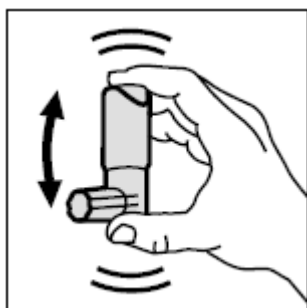


Figure 1

- 3) Breathe out deeply.
- 4) Hold the metered aerosol (as shown in Fig 2), and close lips over the mouthpiece. The arrow and the base of the container should be pointing upwards.

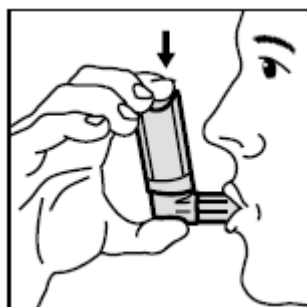


Figure 2

- 5) Breathe in as deeply as possible, pressing the base of the container firmly at the same time, this releases one metered dose. Hold the breath for a few seconds, then remove the mouthpiece from the mouth and breathe out. The same action should be repeated for a second inhalation.
- 6) Replace the protective cap after use.

Note: The mouthpiece should always be kept clean and can be washed in warm water. If soap or detergent is used, the mouthpiece should be thoroughly rinsed in clear water.

Warning

The container is under pressure and should on no account be opened by force or exposed to temperatures exceeding 50°C. As the container is not transparent it is not possible to see when the contents are used up, but shaking the container will show if there is any remaining fluid.

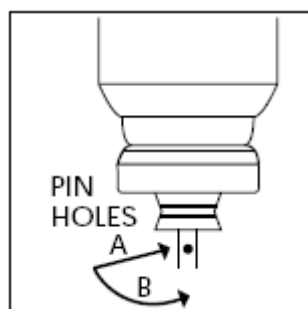
Store below 30° C

Care and Cleaning

How to maintain your COMBIVENT Inhaler

In order to obtain the best service from your COMBIVENT inhaler, these simple directions on maintenance should be carefully observed. The most common causes of failure of the metering device of the inhaler to function are:

- 1) Blockage of the pinholes in the stem of the vial (A, B).



- 2) A dirty or blocked mouthpiece.

There are two pinholes in the stem of the vial, hole A at the side near the base of the stem and hole B, at the end of the stem (see diagram). If these holes become blocked, pull out the vial from the mouthpiece and clear them by rinsing well in clean lukewarm water. When dry, replace the vial in the mouthpiece. The mouthpiece of the inhaler should be kept clean by washing regularly in warm soapy water, rinsing in clear water and drying on a clean tissue. Remember to take out the vial before you wash the mouthpiece. Always replace the protective cap on the mouthpiece after usage to prevent the inside of the apparatus becoming dusty.

When removing the vial from the mouthpiece, pull out carefully to avoid bending the stem. Never press the stem against the firm surface to check for function. This may bend the stem and lead to malfunction of the inhaler. Reassemble the inhaler for use by fitting the stem of the vial into the inner hole, at the base of the long end of the mouthpiece.