

# Combivent<sup>®</sup>

## Unit Dose Vial (UDV)

*Ipratropium bromide and Salbutamol sulfate*

### Consumer Medicine Information

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This leaflet answers some common questions about Combivent UDV.

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 Combivent UDV.

You may need to read it again later.

#### To find out more about Combivent UDV

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 UDV.

#### 1. What Combivent UDV is used for

Combivent UDV is used to make breathing easier for people with an airways condition known as chronic obstructive pulmonary disease (COPD) (such as bronchitis, emphysema and related conditions).

Combivent UDV 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 UDV contains two active medications: ipratropium bromide and salbutamol sulfate. These medications act in different ways. When used in combination, the improvement in breathing is better than when each medication is used alone.

#### 2. Before you use Combivent UDV

##### 2a) When you must not use Combivent UDV

Only use Combivent UDV 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 UDV if you are allergic to it or to any of the ingredients.

These ingredients are listed in full at the end of this leaflet (See 7b ingredients).

In some cases you should not use Combivent UDV if you are allergic to certain other medicines.

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

Do not use Combivent UDV if you have certain heart conditions known as "hypertrophic obstructive cardiomyopathy" or "tachyarrhythmia".

You should never use Combivent UDV after the EXPIRY DATE on the vial or carton.

##### 2b) Before you start to use Combivent UDV

It is essential that your doctor knows your medical history before prescribing Combivent UDV.

Before using Combivent UDV you must tell your doctor if you have, or have had, any of the following conditions:

- high pressure in the eye (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;
- asthma.

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 UDV 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.

### 2c) 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.

### 2d) 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.

### 2e) Children

Combivent UDV is not recommended for use in children.

## 3. Using Combivent UDV

### 3a) How to use Combivent UDV

Instructions on how to use Combivent UDV are printed at the end of this leaflet.

You must ensure that a nebuliser mask is properly fitted to your nose and mouth before nebulising and inhaling Combivent UDV.

There have been some reports of eye problems as a result of the mist contacting the eyes. Proper fitting of the nebuliser mask to your nose and mouth will prevent the mist from contacting your eyes. Patients with an eye condition called "glaucoma" should be extra careful, as contact of the Combivent UDV mist with the eyes may worsen this condition.

### 3b) Recommended dose

Adults:

The recommended dose is as follows: the contents of 1 UDV (2.5 mL) nebulised until the entire volume of solution is inhaled, three to four times daily.

If your doctor has prescribed a different dose, you should ask for further information from your doctor or pharmacist.

### 3c) If you forget to take a dose

It is important to use Combivent UDV 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.

### 3d) Overdose

Seek medical advice if you have used more than the recommended or prescribed dose of Combivent UDV and you experience signs of overdose as listed below.

Advice can be provided by a doctor, pharmacist or Poisons Information Centre.

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

## 4. While you are using Combivent UDV

It is very important to follow the Directions for Use carefully and fit the nebuliser mask to your nose and mouth properly to prevent contact of the solution or nebulised mist 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 UDV.

This is because there have been isolated reports of narrow-angle glaucoma with the use of Combivent UDV.

If your breathing becomes more difficult while you are using Combivent UDV, 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 UDV.

This applies to all medicines obtained with or without a doctor's prescription.

## 5. 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

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risks of you taking Combivent UDV 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 more frequently reported side effects of Combivent UDV are:

- headache;
- dizziness;
- nervous feeling;
- fast and strong heart beat; and
- shaky feeling.

Less frequently reported side effects of Combivent UDV include:

- cough and throat irritation;
- nausea;
- vomiting;
- sweating; and
- muscle weakness and cramps.

There are isolated reports of:

- eye problems; and
- mental disturbances.

Rare side effects include:

- change in bowel movements;
- difficulty in passing urine;
- changes in blood pressure;
- irregular heart beat;
- low blood potassium levels; and
- skin or allergic reactions (swollen tongue and lips, mouth ulcers and rash on the face).

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

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 UDV.

## 6. After using Combivent UDV

### 6a) Storage

Combivent UDV should be kept in a cool, dry place where the temperature stays below 25°C.

Do not store in direct sunlight or heat.

For example, do not leave it in the car on hot days.

Keep your Combivent UDV where children cannot reach it.

### 6b) Disposal

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

### 7c) Manufacturer

Combivent UDV is made in the United Kingdom and supplied in Australia by:

BOEHRINGER INGELHEIM PTY LIMITED  
(ACN 000 452 308)  
85 Waterloo Road  
NORTH RYDE NSW 2113

Logo

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## 7. Product Description

### 7a) What Combivent UDV is

Combivent is the brand name of your medicine. It comes in Unit Dose Vials (UDVs) which contain 2.5 mL of solution. The UDVs are available in packs of (10 and) 30 and each pack is labelled with the Australian Registration Number AUST R 67267.

### 7b) Ingredients

Each Combivent UDV (2.5 mL) contains ipratropium bromide 0.52 milligrams [equivalent to ipratropium bromide (anhydrous) 0.5 milligrams] and salbutamol sulfate 3.01 milligrams [equivalent to salbutamol 2.5 milligrams]. The other ingredients in Combivent UDV are sodium chloride, hydrochloric acid and purified water.

# Combivent<sup>®</sup>

## Unit Dose Vial (UDV)

*Ipratropium bromide and  
Salbutamol sulfate*

### Directions for Use

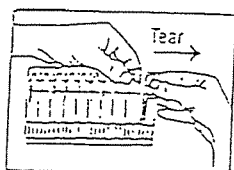
Combivent Unit Dose Vials are intended for inhalation with suitable nebulising equipment and must not be swallowed.

Diluted solutions should be freshly prepared before use. At the end of inhalation, leftover solution from the nebuliser bowl should be discarded.

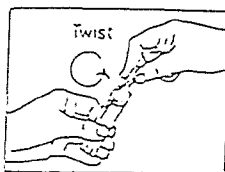
As no testing has been conducted with other nebulising solutions, it is recommended not to mix Combivent UDV solution with other drugs in the same nebuliser.

Take the following steps in using Combivent UDV and if you have any problems, ask your doctor or pharmacist for assistance.

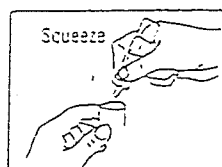
1. Get your nebuliser ready by following the manufacturer's instructions and the advice of your doctor.
2. Carefully tear a new vial from the strip. Never use one that has been opened already.



3. Open the vial by twisting off the top, always taking care to hold it in an upright position.



4. Squeeze the contents of the vial into the nebuliser bowl. If dilution is necessary this should be carried out using normal saline and as instructed by your doctor.



5. Assemble the nebuliser and use it as directed by your doctor.
6. After nebulisation follow the manufacturer's instructions about cleaning your nebuliser.