PART III: CONSUMER INFORMATION

[Pr]Combivent® UDV

Ipratropium Bromide (as Monohydrate) and Salbutamol (as Salbutamol Sulfate) Nebulizer Solution

Read this carefully before you start taking COMBIVENT UDV and each time you get a refill. This leaflet is a summary and will not tell you everything about COMBIVENT UDV. Talk to your doctor, nurse, or pharmacist about your medical condition and treatment and ask if there is any new information about COMBIVENT UDV.

ABOUT THIS MEDICATION

What the medication is used for:
COMBIVENT UDV is used to treat the wheezing or shortness of breath caused by COPD (chronic obstructive pulmonary disease which includes chronic bronchitis and emphysema).

What it does:
COMBIVENT UDV is a combination of two drugs that are bronchodilators: ipratropium bromide (an anticholinergic) and salbutamol (a beta-agonist). COMBIVENT UDV works by relaxing the muscle surrounding the bronchi (airways in the lungs) and therefore helps to ease breathing problems.

You may already be familiar with one or both of these bronchodilators, since they are also available separately, with a prescription as ipratropium bromide and salbutamol.

When it should not be used:
Do not take COMBIVENT UDV

- if you are allergic to ipratropium bromide or other drugs which are anticholinergic (contain atropine or its derivatives), salbutamol sulfate, or to any component of COMBIVENT UDV (see "**What the non-medicinal ingredients are"**);
- if you have a fast or irregular heart beat or have a thickened heart muscle due to various conditions;
- if you are under 18 years of age.

What the medicinal ingredients are:
Ipratropium bromide monohydrate and salbutamol sulfate.

What the non-medicinal ingredients are:
Hydrochloric acid, purified water and sodium chloride.

What dosage forms it comes in:
COMBIVENT UDV is supplied in unit dose vials. The vials contain a combination of two bronchodilators:

- 0.50 mg ipratropium bromide (as ipratropium bromide monohydrate) and
- 2.5 mg salbutamol (as salbutamol sulfate).

Combivent UDV is for administration by inhalation by ventilator or compressor-driven nebulizer.

WARNINGS AND PRECAUTIONS

The solution is intended for inhalation only. Do not inject or drink.

Do not let the nebulized mist get into your eyes as this may cause blindness known as acute angle glaucoma. This may present as eye pain or discomfort, blurred vision, visual halos or coloured images in association with red eyes. If any combination of these symptoms occurs, seek immediate medical attention. Patients with glaucoma should use swimming goggles or a nebulizer with a mouthpiece to prevent nebulized solution getting into the eyes.

BEFORE you use COMBIVENT UDV talk to your doctor or pharmacist if you:

- are pregnant or intend to become pregnant;
- are breast feeding;
- are having treatment for a thyroid or adrenal gland condition;
- are having treatment for high blood pressure, angina or a heart problem;
- have diabetes;
- have low levels of potassium in your blood (hypokalemia), especially if you are taking:
    - drugs known as xanthine derivatives (such as theophylline)
    - steroids to treat asthma
    - water pills (diuretics)
- have eye problems, such as glaucoma, or eye pain;
- are taking any other medications including eye drops or any medications you can buy without a prescription;
- have difficulty in urination;
- have enlarged prostate;
- have any allergies or reactions to foods or drugs;
- have a history of convulsions (uncontrolled shaking or seizures);
- have liver or kidney disease.

Contact your doctor immediately if:

- you require more than one dose to relieve your breathing problems;
- your shortness of breath becomes worse;
- you don't get the same benefit from your medicine as you did before;
- you have breathing difficulties and chest pain;
- you experience difficulty with urination.

COMBIVENT UDV may cause dizziness, difficulty in focusing the eye, dilated pupils, and blurred vision. You should not drive or operate machinery if this occurs.

The use of COMBIVENT UDV may test positive for performance enhancement (doping) in athletic competition.

INTERACTIONS WITH THIS MEDICATION

Do not mix COMBIVENT UDV with other drugs in the same nebulizer.

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with COMBIVENT UDV:

- digitalis;
- other anticholinergic drugs, such as ipratropium bromide and other beta$_2$-adrenergic agents such as salbutamol, the individual ingredients of COMBIVENT UDV;
- beta blockers, such as propranolol;
- xanthine derivatives such as theophylline;
- monoamine oxidase inhibitors such as isocarboxazid;
- tricyclic antidepressants such as amitriptyline;
- epinephrine;
- certain diuretics or "water pills" such as furosemide, hydrochlorothiazide.

PROPER USE OF THIS MEDICATION

COMBIVENT UDV **should only be inhaled** from a nebulizer. It must not be injected or swallowed.

Do not let the COMBIVENT UDV or the mist produced by the nebulizer, get in your eyes.

Use your nebulizer in a well ventilated room. Some of the mist will be released into the air and may be breathed in by others.

Use COMBIVENT UDV only as directed by your doctor. During administration your doctor may want to monitor your blood.

Treatment with COMBIVENT UDV is to be initiated and administered under medical supervision (e.g. in the hospital setting). Home based treatment can be recommended in exceptional cases (severe symptoms or experienced patients requiring higher doses) when a low dose rapid acting beta-agonist bronchodilator has been insufficient in providing relief after consultation with an experienced physician. Administration should be stopped when sufficient symptom relief is achieved.

COMBIVENT UDV has been prescribed to treat your current condition. DO NOT give it to other people. Always use COMBIVENT UDV exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

COMBIVENT UDV should be used only in a properly functioning and regularly maintained nebulizer or an intermittent positive pressure ventilator. Before starting treatment, be certain that you are completely familiar with the use and proper care of your nebulizer. The content of the unit dose vials does not need to be diluted for nebulization.

Not recommended for use in children and adolescents under 18 years of age.

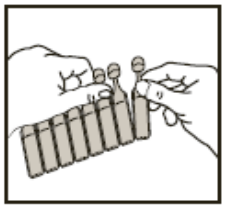
Usual Adult dose:

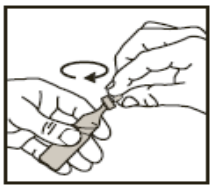
The recommended dosage is 1 unit dose vial (0.50 mg ipratropium bromide (as ipratropium bromide monohydrate) and 2.5 mg salbutamol (as salbutamol sulfate) in 2.5 mL) three or four times daily.

If one unit dose vial does not improve your breathing difficulties, you may need another unit dose vial. If this is the case, you should contact your doctor or the nearest hospital.

Your doctor or pharmacist will tell you how to prepare your COMBIVENT UDV nebulizer solution. Your doctor or pharmacist might instruct you to use sterile sodium chloride solution (0.9%) to dilute the COMBIVENT UDV solution. If you are told to dilute COMBIVENT UDV solution, you must do so immediately before you plan to use the solution. If necessary, doses may be diluted to a total nebulization volume of 3-5 mL with preservative free 0.9% sterile sodium chloride solution and used immediately. Discard any unused solution. Nebulize over 10-15 minutes at gas flow of 6-10L/min. Repeat every six hours as necessary.

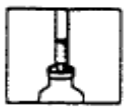
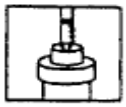
Please read and carefully follow these instructions:

1. 
Open the pouch foil and detach one plastic vial by pulling it firmly from the strip.

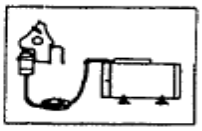
2. 
Open the vial by twisting off the top. It is important that you use the contents of the vial as soon as possible after opening it.

3. 
Squeeze the contents of the plastic vial into your nebulizer chamber. If your doctor has instructed you to use less than one complete vial, use a syringe to withdraw the prescribed dose.

Any solution left in the plastic vial must be thrown away.

4.  

Using a syringe, add sodium chloride solution to the chamber if you have been directed to do so by your pharmacist or physician.

5.  

Gently shake the nebulizer chamber and connect it to the mouthpiece or face mask. Then connect the nebulizer tube to the air or oxygen pump and begin therapy.

6. 

Breathe calmly and deeply through the mask or mouthpiece until no more mist is formed in the nebulizer chamber. This usually takes 10-15 minutes.

It is very important to adjust the face mask, if required, to prevent the mist from getting in your eyes.

7. Follow the instructions provided by the nebulizer and air pump manufacturers for the proper care and maintenance of the equipment. Keep the nebulizer, nebulizer tube and face mask clean to minimize microbial contamination.

Make sure you use the vial soon after opening and use a fresh vial each time to prevent contamination (growth of harmful microorganisms). Partly used, opened or damaged unit dose vials should be discarded.

Do not mix COMBIVENT UDV with other drugs in the same nebulizer.

Overdose:

In case of an overdose, contact your doctor, or the Regional Poison Control Center, or go to the nearest hospital emergency department.

Missed dose:

If a dose is missed and no symptoms occur, the regular next dose according to the dosing schedule should be taken. If a dose is missed and respiratory symptoms are experienced, the missing dose should be taken and the dosing schedule according to the recommended dosage should be resumed.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- wheezing after inhalation;
- headache, dizziness;
- nausea (feeling sick), digestive problems like constipation, diarrhoea and vomiting;
- muscle problems such as cramps weakness, pain, feeling weak, tremor (shaking);
- feeling nervous;
- mental disorder;
- impaired voice sounds;
- increased sweating;
- bronchitis and upper respiratory tract infection (a cold)
- throat irritation, cough, dry mouth or throat, bad taste- sucking on a sour candy or rinsing your mouth may help.

Check with your doctor if the dry mouth or bad taste persist or if you experience constipation for a prolonged period of time.

COMBIVENT UDV contains a beta-agonist, and taking additional doses in the form of other single agent, beta-agonists (fenoterol, salbutamol, etc.) could cause harmful effects on the heart, lungs and circulatory system. Therefore do not take additional bronchodilators by inhalation with COMBIVENT UDV unless instructed to do so by your doctor or pharmacist.

Stop taking the medication and tell your doctor immediately if you notice any of the following:

- you are wheezy or have any other difficulties in breathing;
- you are having an allergic reaction – the signs may include skin rash, itching and nettle rash. In severe cases the signs include swelling of your tongue, lips and face, sudden difficulties in breathing and reduction of your blood pressure.

COMBIVENT UDV can cause abnormal blood test results for hypokalemia and/or ketoacidosis. Your doctor will decide when to perform blood tests and will interpret the results.

If you have any questions about COMBIVENT UDV or your nebulizer, contact your doctor or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		**Talk with your doctor or pharmacist**		**Stop taking drug and seek immediate medical help**
		Only if severe	**In all cases**	
Uncommon	**Bronchospasm:** Increased wheezing or tightness in the chest, difficulty in breathing, coughing bouts			✓
	Shortness of breath			✓
	Hypotension or Hypertension, Changes in blood pressure: dizziness, fainting, lightheadedness			✓
	Skin rash			✓
Rare	**Allergic Reaction:** rash, hives, swelling of the face, lips, mouth, tongue or throat, difficulty swallowing or breathing, choking due to swelling of the muscles around the voice box			✓
	Fast or irregular heart beat / chest pain			✓
	Eye Disorders: new or worsened pressure in your eyes, eye pain or discomfort, blurred vision, seeing halos or rainbows around items or red eyes			✓
	Urinary Retention: difficulty and pain when passing urine, urinating frequently, urination in a weak stream or drips			✓
	Muscle pain, weakness or spasms; paralysis			✓
	Myocardial Ischaemia: decreased blood flow to the heart leading to angina (chest pain), shortness of breath, or a heart attack			✓
	Angina: Chest pain			✓
	Decreased levels of potassium in the blood: irregular heartbeats, muscle weakness and generally feeling unwell			✓

This is not a complete list of side effects. For any unexpected effects while taking COMBIVENT UDV, contact your doctor or pharmacist.

HOW TO STORE IT

Unopened unit dose vials of COMBIVENT UDV should be stored at room temperature (15-25°C). The vials should be protected from heat and light. Do not use if solution is discoloured. Keep out of reach of children.

Partly used, opened or damaged unit dose vials should be discarded.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - Fax toll-free to 1-866-678-6789, or
  - Mail to:
  Canada Vigilance Program
  Health Canada
  Postal Locator 0701E
  Ottawa, Ontario
  K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: http://www.boehringer-ingelheim.ca or by contacting the sponsor, Boehringer Ingelheim (Canada) Ltd., at: 1-800-263-5103 Ext.84633 (Medical Information).

Please visit our website to see if more up-to-date information has been posted.

This leaflet was prepared by Boehringer Ingelheim (Canada) Ltd.

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