PATIENT INFORMATION LEAFLET

Read this leaflet carefully before you start using this medicine.

- **Keep this leaflet. You may need to read it again.**
- **If you have further questions, please ask your doctor or your pharmacist.**
- **This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.**

SCHEDULING STATUS: S3

PROPRIETARY NAME, STRENGTH AND PHARMCEUTICAL FORM

ADCO-COMBINEB (Inhalant Solution)

WHAT ADCO-COMBINEB CONTAINS

The active ingredients of ADCO-COMBINEB are ipratropium bromide equivalent to 0,5 mg ipratropium bromide anhydrous and salbutamol sulphate equivalent to 2,5 mg salbutamol base.

The inactive ingredients are sodium chloride (isotonicity agent) and hydrochloric acid (for pH adjusment).

The solution is isotonic and preservative free.

WHAT ADCO-COMBINEB IS USED FOR

The active ingredients ipratropium bromide and salbutamol sulphate both belong to the group of medicines known as bronchodilators. They both produce bronchodilation, ie. they open up the airways. This results in easier breathing for patients with asthma, chronic bronchitis, emphysema (all lung disorders) and any condition that obstructs the airways.

This medicinal product is for inhalation only.

BEFORE YOU USE ADCO-COMBINEB

The use of this medicine is not recommended for children under the age of 12 years.

Do not use ADCO-COMBINEB:

- If you are hypersensitive (allergic) to ipratropium bromide and/ or salbutamol sulphate,
- If you have hypertrophic obstructive cardiomyopathy, tachyarrhythmia, coronary insufficiency (heart conditions) or hypertension (high blood pressure),
- If you have angle-closure glaucoma (eye condition),
- If you suffer with urinary retention.

Take special care with ADCO- COMBINEB:

- If you have glaucoma, ensure that the mist or solution does not enter your eyes,
- If difficulty in breathing persists after using this medication, or if condition becomes worse, consult your doctor immediately,
- If you require higher doses of ADCO-COMBINEB than what is recommended to control your symptoms, consult a doctor immediately.

When using ADCO-COMBINEB, it is very important that your doctor knows whether you have any of the following conditions:

- Prostatic hyperplasia, hyperthyroidism (increased thyroid activity), myocardial insufficiency, arrhythmias, susceptibility to QT-interval prolongation, hypertension, diabetes mellitus, bladder-neck obstruction and pheochromocytoma,
- If you have history of angle-closure glaucoma (increased pressure in eyes), you might be at an increased risk of developing glaucoma when nebulised ipratropium bromide and salbutamol sulphate are used together,
- If you have cystic fibrosis and spastic diplegia, you may be more prone to paralytic ileus development (gastro-intestinal disorder).

Pregnancy and Breast-feeding:

Safety of this medicine in pregnancy and breast-feeding has not been established.

If you are pregnant or breast feeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Using other medicines with ADCO-COMBINEB:

When using ADCO-COMBINEB, it is very important that your doctor know if you using any of the following:

- Corticosteroids, diuretics, xanthines or digoxin - they increase the risk of hypokalaemia (low potassium levels) which can affect the heart.
- Tricyclic antidepressants and monoamine oxidase inhibitors – the effects of ADCO-COMBINEB may be enhanced.
- Halothane, trichloroethlyene and enflurane – inhalation of these anaesthetics when using ADCO-COMBINEB can affect the heart.

Always tell your healthcare professional if you are taking any other medicine (This includes complementary or traditional medicines)

HOW TO USE ADCO-COMBINEB

Always use ADCO-COMBINEB exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose for Adults and Children over 12 years is:

Treatment of acute attacks: One ampoule is sufficient for prompt symptom relief in most cases. If in very severe cases, two ampoules are required for symptom relief, these should be administered under medical supervision.

Maintenance treatment: One ampoule three to four times daily.

DO NOT EXCEED THE RECOMMENDED DOSE.

ADCO-COMBINEB is to be inhaled only. Instructions for use:

1. Prepare the nebuliser for filling, according to the instructions provided by the manufacturer or your doctor.
2. Remove one ampoule by detaching from the strip.
3. Flick the top of the ampoule to dispel any fluid in the neck.
4. Detach top portion by twisting.
5. Squeeze the contents of the ampoule into the nebuliser reservoir.

6. Assemble the nebuliser and use as directed.
7. After use throw away any solution left in the reservoir and clean the nebuliser, following the manufacturer's instructions.

Since the ampoules do not contain a preservative, it is important that the contents of each ampoule are used up immediately after opening and that a fresh ampoule is used for each time to avoid contamination. Partly used, opened or damaged ampoules should be thrown away.

ADCO-COMBINEB inhalant solution must not be mixed with other medicines in the same nebuliser reservoir. If necessary, it should be diluted using only sterile sodium chloride 0,9 % solution under medical supervision.

If you use more ADCO-COMBINEB than you should:

You may experience the following:

- More frequently: Hyperglycaemia, hypokalaemia, hypotension, lactic acidosis, tachycardia, trembling, vomiting, palpitation, hypertension, widening of the pulse pressure and flushing.
- Less frequently: Hallucinations, paranoia, seizures, tachyarrhythmias.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the hospital or poison control center.

If you forget to use ADCO-COMBINEB:

Do not use a double dose to make up for the forgotten individual doses.

POSSIBLE SIDE EFFECTS

ADCO-COMBINEB can have side effects.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- difficulty in breathing increases.
- angioedema (swelling of face, lips or eyelids), skin rash, urticaria (hives),
- chest discomfort or pain,
- changes in the way your heart beats, for example, if you notice it beating faster,

- changes in blood pressure,
- blurred vision or other changes in vision, burning eyes, eye pain (signs of glaucoma),
- hypokalaemia (low potassium levels), hyperglycaemia (high blood glucose levels).

These are all serious side effects. You may need urgent medical attention. Serious side effects are rare.

Tell your doctor if you notice any of the following:

- nausea (feeling sick) or vomiting,
- fine tremor of muscles (particularly the hands),
- headache or dizziness,
- nervousness,
- dry mouth,
- coughing,
- change in sense of taste,
- urinary retention or constipation,
- nasal dryness.

These are all mild side effects of ADCO-COMBINEB.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while using this medicine, please consult your doctor, pharmacist or other health care professional for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF ADCO-COMBINEB:

Keep all medicines out of the reach and sight of children.

Store the ampoules in the outer packaging below 25 °C, until required for use.

Protect from light. Do not freeze. Do not use the medicine after the expiry date stated on the ampoule.

Return all unused medicine to your pharmacist. Do not dispose of unused medicines in drains or sewerage systems, eg. toilets.

PRESENTATION OF ADCO-COMBINEB

Strips of 10 ampoules enclosed in packs of 60 ampoules. Each plastic low density polyethylene ampoule contains 2,5 ml of solution.

IDENTIFICATION OF ADCO- COMBINEB

ADCO-COMBINEB low density polyethylene ampoules contain a clear, colourless or almost colourless solution.

REGISTRATION NUMBER/REFERENCE NUMBER

A39/10.2.1/0373

NAME AND ADDRESS OF REGISTRATION HOLDER

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