Combivent Metered Aerosol : data sheet.

Combivent® Metered Aerosol

DATA SHEET

Presentation
Pressurised metered dose inhaler, 10 ml vial (200 metered doses) available as a complete unit with mouthpiece. Each metered dose contains ipratropium bromide 20 micrograms and salbutamol sulphate 120 micrograms equivalent to salbutamol 100 micrograms.

Uses
Action: Ipratropium bromide is an anticholinergic bronchodilator and salbutamol is a β_2-adrenergic bronchodilator. Both agents act on airway smooth muscle resulting in relaxation.

Indication: For the treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD) in patients who require regular treatment with both ipratropium and salbutamol.

Dosage and Administration

Adults: (including elderly patients)	Two inhalations four times a day
Children:	There is no experience of the use of Combivent in children below the age of 12 years.

Contra-indications, warnings etc.
Contra-indications: Known hypersensitivity to any of the components or to atropine or its derivatives.

Precautions: When the contents of metered aerosols containing ipratropium bromide have been inadvertently sprayed into the eye, there have been rare reports of ocular effects, e.g. mydriasis, blurring of vision and eye pain. Care must be taken to prevent Combivent from entering the eye. Should patients develop effects in the eye, they should be warned to seek medical advice.

Patients must be instructed in the correct administration of Combivent metered aerosol.

In the following conditions Combivent should only be used after careful risk/benefit assessment: hypertrophic obstructive cardiomyopathy, tachyarrhythmia, insufficiently controlled diabetes mellitus, recent myocardial infarction and/or severe organic heart or vascular disorders, hyperthyroidism.

The patient should be instructed to consult a doctor immediately in the event of acute, rapidly worsening dyspnoea. In addition, the patient should be warned to seek medical advice should a reduced response become apparent.

Potentially serious hypokalaemia may result from β_2-agonist therapy. Particular caution is advised in severe airway obstruction as this effect may be potentiated by concomitant treatment with xanthine derivatives, steroids and diuretics. Additionally, hypoxia may aggravate the effects of

hypokalaemia on cardiac rhythm. It is recommended that serum potassium levels are monitored in such situations.

Beta-adrenergics, xanthine derivatives and corticosteroids may enhance the effect of Combivent. The concurrent administration of other beta-mimetics, systemically absorbed anticholinergics and xanthine derivatives may increase the side effects. A potentially serious reduction in effect may occur during concurrent administration of beta-blockers.

Anticholinergic effects of other drugs can be enhanced.

Pregnancy and lactation: Ipratropium bromide has been in general use for several years and there is no definite evidence of ill consequence during pregnancy; animal studies have shown no hazard.

Salbutamol has been in widespread use for many years without apparent ill consequence during pregnancy. There is inadequate published evidence of safety in the early stages of human pregnancy but in animal studies there has been evidence of some harmful effects on the foetus at very high dose levels.

As with all medicines, Combivent should not be used in pregnancy, especially the first trimester, unless the expected benefit is thought to outweigh any possible risk to the foetus. Similarly, Combivent should not be administered to breast-feeding mothers unless the expected benefit is thought to outweigh any possible risk to the neonate.

Side-effects: In common with other beta-agonists more frequent undesirable effects of Combivent are fine tremor of skeletal muscles and nervousness, less frequent are tachycardia, dizziness, palpitations or headache, especially in hypersensitive patients.

In isolated cases there may be local reactions such as dryness of the mouth, throat irritation, or allergic reactions.

As with other bronchodilators, in some cases cough, in very rare instances paradoxical bronchoconstrictions have been observed.

Use of anticholinergic agents (e.g. ipratropium bromide) may precipitate urinary retention, in particular in patients with pre-existing outflow tract obstruction.

Overdosage: The effects of overdosage are expected to be primarily related to salbutamol because acute overdosage with ipratropium bromide is unlikely as it is not well absorbed systemically after inhalation or oral administration.

Manifestations of overdosage with salbutamol may include anginal pain, hypertension, hypokalaemia and tachycardia. The preferred antidote for overdosage with salbutamol is a cardioselective beta-blocking agent but due care and attention should be used in administering these drugs in patients with a history of bronchospasm.

Pharmaceutical Precautions

Store below 30^{O}C. Protect from direct sunlight, heat and frost. The vials should not be punctured or incinerated even when apparently empty.

Legal Category
POM

Package Quantities
10ml vial (200 metered doses) (OP) complete with mouthpiece.

Further Information
Nil.

Product Licence Number
0015/0191

Product Licence Holder
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Ingelheim