PROFESSIONAL INFORMATION

SCHEDULING STATUS S3

1. NAME OF THE MEDICINE

ADCO IPRATROPIUM 0,25 mg/2 ml (Inhalant solution)

ADCO IPRATROPIUM 0,5 mg/2 ml (Inhalant solution)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ADCO IPRATROPIUM 0,25 mg/2 ml

Each 2 ml solution contains 0,25 mg ipratropium bromide

ADCO IPRATROPIUM 0,5 mg/2 ml

Each 2 ml solution contains 0,5 mg ipratropium bromide

Excipient(s) with known effect:

- Sugar content: sugar free

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

ADCO IPRATROPIUM is a clear, colourless to pale yellow solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

ADCO IPRATROPIUM is indicated for maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease, including chronic bronchitis and pulmonary emphysema. For the treatment of acute exacerbations of asthma (bronchospasm), **ADCO IPRATROPIUM** is used in conjunction with inhaled beta-agonists.

4.2 Posology and method of administration

Posology

The recommended dosage is:

Adults

One ampoule of **ADCO IPRATROPIUM 0,5 mg/2 ml** three or four times daily, or two ampoules of **ADCO IPRATROPIUM 0,25 mg/2 ml** three or four times daily. Inhalation may be repeated on a 2 hourly basis up to a maximum of six times a day.

Paediatric population

One **ADCO IPRATROPIUM 0,25 mg/2 ml** ampoule up to four times daily.

Method of administration

For oral inhalation only.

ADCO IPRATROPIUM may be used by intermittent administration from an intermittent positive pressure ventilator or from suitable nebulisers.

It is important that the contents of each ampoule are used up immediately after opening. Use a fresh ampoule for each dose. Partly used, opened or damaged ampoules should be discarded.

For precaution to be taken before manipulating or administering the product, see section 6.6.

4.3 Contraindications

Known hypersensitivity to ipratropium bromide, or atropinics.

4.4 Special warnings and precautions for use

Patients must be instructed in the correct administration of **ADCO IPRATROPIUM** inhalation solution. Care must be taken not to allow the solution or mist to enter into the eyes. It is recommended that the nebuliser solution be administered via a mouth piece. If this is not available and a nebuliser mask is used, it must fit properly. Patients who may be predisposed to glaucoma should be warned specifically to protect their eyes.

ADCO IPRATROPIUM should be used with caution in patients predisposed to narrow-angle glaucoma, or with prostatic hypertrophy or bladder-neck obstruction.

Patients with cystic fibrosis may be prone to gastro-intestinal motility disturbances.

4.5 Interactions with other medicines and other forms of interaction

Beta-adrenergics and xanthine preparations may intensify the bronchodilatory effect.

4.6 Fertility, pregnancy and lactation

The safety of this preparation in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

ADCO IPRATROPIUM has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

a. Summary of the safety profile

Not applicable

b. Tabulated summary of adverse reactions

Side effects have been ranked according to frequency within each System Organ Class. The following adverse reaction have been reported with **ADCO IPRATROPIUM**.

System Organ class	**MedDRA Preferred Term**	**Frequency**
Cardiac disorders	Tachycardia and palpitations, which are reversible	Less frequent
Eyesight disorders	Ocular accommodation disturbances, which is reversible	Less frequent
Gastrointestinal disorders	Nausea and dryness of mouth	Frequent
	Gastro-intestinal motility disturbances, which is reversible	Less frequent
Immune system disorders	Hypersensitivity reactions may occur after administration of **ADCO IPRATROPIUM** inhalation solution, as demonstrated by less frequent cases of urticaria, angioedema, rash, bronchospasm and oropharyngeal oedema	Less frequent
Renal and urinary disorders	Urinary retention, the risk of which may be increased in patients with pre-existing outflow tract obstruction	Less frequent

Respiratory, thoracic and mediastinal disorders	Cough and, less common, paradoxical bronchoconstriction has been observed	Frequency unknown
Vascular disorders	Headache	Frequent

Post-marketing experience

There have been isolated reports of ocular complications (i.e. mydriasis, increased intraocular pressure, narrow-angle glaucoma, eye pain) when aerosolised **ADCO IPRATROPIUM** either alone or in combination with an adrenergic beta 2-agonist has escaped into the eyes. Eye pain or discomfort, blurred vision, visual halos or coloured images in association with red eyes from conjunctival and corneal congestion may be signs of acute narrow-angle glaucoma. Should any combination of these symptoms develop, treatment with miotic drops should be initiated and specialist advice sought immediately.

c. Description of selected adverse reactions

Not applicable

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8.

For reporting of side effects directly to the HCR, contact +27 11 635 0134 or email Adcock.aereports@adcock.com.

4.9 Overdose

Anti-cholinergic side effects may occur. Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group and ATC code: Anticholinergics, ATC code: R03BB.

Ipratropium is a quaternary ammonium compound with anticholinergic properties. Ipratropium does not affect mucociliary transport in the respiratory tract. Ipratropium has also been shown to have no effect on sputum volume or sputum viscosity. Tachyphylaxis does not seem to be associated with prolonged use of ipratropium. Since it acts directly on the airwaves, ipratropium is well tolerated without producing atropine-like systemic side effects. The onset of action is within 5 to 15 minutes, and the duration of action, is about 3 to 4 hours in the majority of patients, but up to 6 to 8 hours in some patients.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride, sodium hydroxide, water for injections.

6.2 Incompatibilities

This medicine must not be mixed with other medicines except those mentioned in section 6.6

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 25 °C and protect from light.

6.5 Nature and contents of container

ADCO IPRATROPIUM 0,25 mg/2 ml and **ADCO IPRATROPIUM 0,5 mg/2 ml** are available in cartons containing 60 x 2 ml polyethylene ampoules.

60 x 2 ml polyethylene ampoules are packed in a foil pouch.

6.6 Special precautions for disposal and other handling

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 adjacent one
3. Flick the top of the ampoule smartly to dispel any fluid in the neck
4. Detach top portion by twisting
5. Squeeze the contents of the ampoule into the reservoir of the nebuliser
6. Assemble the nebuliser and use as directed. After use, throw away any solution left in the reservoir and clean the nebuliser, following the manufacturer’s instructions.

Patients must be instructed on the correct use of the inhalant solution and nebuliser, and warned against accidental release of the contents into the eyes.

Ipratropium can be administered combined with an inhaled beta-agonist.

The dose can be diluted with normal saline to a final volume of 2 – 4 ml.
Daily doses exceeding 2 mg in adults and children over 12 years of age, and 1 mg in children under 12 years of age, should be given under medical supervision. Medical advice must be sought, if therapy does not produce a significant improvement or if the patient's condition gets worse.

7. HOLDER OF CERTIFICATE OF REGISTRATION

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8. REGISTRATION NUMBER(S)

ADCO IPRATROPIUM 0,25 mg/2 ml: 33/10.2.1/0270

ADCO IPRATROPIUM 0,5 mg/2 ml: 33/10.2.1/0271

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

ADCO IPRATROPIUM 0,25 mg/2 ml: 31 July 2000

ADCO IPRATROPIUM 0,5 mg/2 ml: 24 August 2000

10. DATE OF REVISION OF THE TEXT

2 November 2023

Botswana ADCO IPRATROPIUM 0,25 mg/2 ml: S2 BOT0901574 ADCO IPRATROPIUM 0,5 mg/2 ml: S2 BOT0901573

Namibia ADCO IPRATROPIUM 0,25 mg/2 ml: NS2 04/10.2.1/1676 ADCO IPRATROPIUM 0,5 mg/2 ml: NS2 04/10.2.1/1677

PI 2 November 2023