FINAL PACKAGE INSERT FOR

IPVENT 40 HFA METERED DOSE INHALER

SCHEDULING STATUS:

S2

PROPRIETARY NAME (AND DOSAGE FORM):

IPVENT 40 HFA (Metered dose inhaler)

COMPOSITION:

IPVENT 40 HFA (Metered Dose Inhaler): Each metered dose contains Ipratropium bromide monohydrate 40 µg.

Propellant: Heptafluoropropane (HFA-propellant-227).

PHARMACOLOGICAL CLASSIFICATION:

A 10.2.1 Bronchodilators – inhalants.

PHARMACOLOGICAL ACTION:

Ipratropium bromide is a quaternary ammonium compound which has anticholinergic (parasympatholytic) properties. The bronchodilation following inhalation of ipratropium bromide is primarily a local, site-specific effect, not a systemic one.

Ipratropium bromide does not affect mucociliary transport and has been shown to have no effect on sputum volume and viscosity.

Ipratropium bromide is poorly absorbed from the gastrointestinal tract and systemic absorption from the lungs, following inhalation, is minimal or absent.

After inhalation, maximal responses usually develop over 30 to 90 minutes, lasting for four to six hours. The elimination half-life of ipratropium is approximately 3 to 4 hours after inhalation.

INDICATIONS:

IPVENT 40 HFA is indicated as bronchodilator for maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

IPVENT 40 HFA is also indicated in the treatment of acute bronchospasm, e.g. associated with asthma, when used concomitantly with inhaled beta-agonists.

CONTRA-INDICATIONS:

IPVENT 40 HFA is contra-indicated in:

- Patients with known hypersensitivity to ipratropium bromide, atropine or its derivates, or to any other components of the product.
- Children, as safety has not been proven.
- Pregnancy and lactation.

WARNINGS:

Only use **IPVENT 20 HFA** with the CIPLA metered dose inhaler mouthpiece (supplied). The mouthpiece of **IPVENT 40 HFA** must never be used with any other

metered dose inhaler, nor must the **IPVENT 40 HFA** metered dose inhaler be used with any mouthpiece other than the one supplied with the product.

Patients who may be predisposed to glaucoma should be warned specifically to protect their eyes (see **"Special Precautions").**

INTERACTIONS:

Beta-adrenergics and methylxanthine preparations may potentiate the bronchodilatory effect. **IPVENT 40 HFA** has been used concomitantly with other medicines commonly used in the treatment of chronic obstructive pulmonary disease, including sympathomimetic bronchodilators, methylxanthines, steroids and disodium cromoglycate without evidence of deleterious medical interactions.

PREGNANCY AND LACTATION:

Safety and efficacy of **IPVENT 40 HFA** during pregnancy and lactation have not been established.

DOSAGE AND DIRECTIONS FOR USE:

Dosage:

The dosage should be adapted to the individual requirements of the patient; patients should also be kept under medical supervision during treatment. Unless otherwise prescribed, the following doses are recommended for adults:

1 metered dose (puff) four times daily. A need for increasing the doses of **IPVENT 40 HFA** suggests that other additional treatment may be needed. A total dose of 8 puffs of **IPVENT 40 HFA** should not be exceeded. Only use the CIPLA **IPVENT 40 HFA**

mouthpiece to administer this medicine.

Instructions for use:

The correct operation of the metered dose inhaler is essential for effective therapy.

Depress the valve twice before the apparatus is used for the first time. Before each use the following rules should be observed:


Fig. 1

1. Shake the bottle before use.
2. Remove protective cap from the mouthpiece.
3. Breathe out fully.
4. Hold the metered dose inhaler as shown in Fig. 1. Place the mouthpiece into the mouth, closing the lips around the mouthpiece. The arrow and the base of the canister should be pointing upwards.
5. Breathe in as deeply as possible and press the base of the canister firmly at the same time - this releases one metered dose. Hold your breath for a few seconds, then remove the mouthpiece from your mouth and breathe out. The same action should be repeated for a second inhalation.
6. Replace the protective cap after use.
7. If you do not use **IPVENT 40 HFA** metered dose inhaler for 3 days or longer, you must spray one dose to waste before use.

The canister is not transparent. It is, therefore, not possible to see when it is empty. The canister will deliver 200 actuations (sprays). When these have all been used, the canister may still appear to contain a small amount of fluid. The canister should, however, be replaced because you may not get the right amount of medication with each spray. The amount of doses in your canister can be checked as follows:

Remove the canister from the plastic mouthpiece and put the canister into a container of water. The contents of the metered dose inhaler can be estimated by observing its position in the water (see Fig. 2).

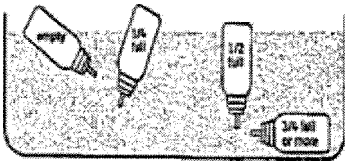


Fig. 2

The mouthpiece should always be kept clean and can be washed with warm water. If soap or detergent is used, the mouthpiece should be thoroughly rinsed in clear water.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Side-effects:

The following side-effects may occur with the use of **IPVENT 40 HFA:**

Immune system disorders:

Less frequent: Hypersensitivity-induced angioedema (including angioedema of tongue, lips and face), and urticaria (including giant urticaria).

The following side-effects have been reported and frequencies are unknown:

Anaphylactic reaction.

Neuropsychiatric system disorders:

Less frequent: Headache, nervousness, trembling, dizziness.

Eye disorders:

Less frequent: Acute eye pain, blurred vision or other changes in vision, burning eyes. See **"Special Precautions".**

Cardiovascular system disorders:

Less frequent: Palpitations.

The following side-effects have been reported and frequencies are unknown:

Supraventricular tachycardia, atrial fibrillation, and increased heart rate.

Respiratory, thoracic and mediastinal disorders:

Frequent: Cough.

Less frequent: Inhalation induced (paradoxical) bronchospasm.

The following side-effects have been reported and frequencies are unknown:

Local irritation and laryngospasm.

Gastrointestinal system disorders:

Frequent: Dryness of mouth, unpleasant taste.

Less frequent: Paralytic ileus, nausea.

The following side-effects have been reported and frequencies are unknown:

Gastrointestinal motility disturbances.

Skin and subcutaneous tissue disorders:

Less frequent: Skin rash, dermatitis, and sweating.

Renal and urinary system disorders:

Less frequent:	Urinary retention. The risk of urinary retention may be increased in patients with pre-existing outflow tract obstruction.

Special Precautions:

IPVENT 40 HFA 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 more prone to gastrointestinal motility disturbances.

Immediate hypersensitivity reactions may occur after administration of **IPVENT 40 HFA** metered dose inhalation, as demonstrated by urticaria, angioedema, rash, bronchospasm and oropharyngeal oedema and anaphylaxis.

There have been reports of ocular complications (i.e. mydriasis, increased intraocular pressure, narrow-angle glaucoma, eye pain) when **IPVENT 40 HFA** has come in contact with the eyes. Thus, patients must be instructed in the correct administration of **IPVENT 40 HFA** metered dose inhaler. Eye pain or discomfort, blurred vision, visual halos or coloured images, in association with red eyes from conjunctival congestion and corneal oedema, 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.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

No symptoms specific to overdosage have been encountered. Minor systemic manifestations of anticholinergic action, including dry mouth, visual accommodation disturbances and tachycardia may occur.

Treatment is symptomatic and supportive.

IDENTIFICATION:

White homogenous suspension aerosol for inhalation, in propellant HFA-227.

PRESENTATION:

Carton containing a metered dose inhaler consisting of a coated aluminium container fitted with a light yellow metering valve and a white plastic actuator.

Each metered dose inhaler contains not less than 200 metered doses.

STORAGE INSTRUCTIONS:

Store at or below 25°C. The canister is pressurised. It should not be broken, punctured or burnt, even when apparently empty.

This container must not be exposed to high temperatures.

STORE THIS MEDICINE OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

43/10.2.1/0544

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

CIPLA MEDPRO (PTY) LTD
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DATE OF PUBLICATION OF THIS PACKAGE INSERT:

APRIL