Final Patient Information Leaflet:
Information for the Patient about
IPVENT 40 HFA METERED DOSE INHALER

Read all of this leaflet carefully before you start taking IPVENT 40 HFA. -

Keep this leaflet, you may need to read it again.

- If you have further questions, please ask your doctor or your pharmacist.

- IPVENT 40 HFA 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:

S2

PROPRIETARY NAME (AND DOSAGE FORM):

IPVENT 40 HFA (Metered dose inhaler)

WHAT IPVENT 40 HFA CONTAINS:

The active substance is ipratropium bromide monohydrate.

Each metered dose contains 40 µg ipratropium bromide monohydrate.

The inactive ingredients are lactose monohydrate and heptafluoropropane (H FA-propellant-227).

WHAT IPVENT 40 HFA IS USED FOR:

IPVENT 40 HFA belongs to a class of medicines called bronchodilators (medicines that open up the airways).

IPVENT 40 HFA is indicated to relieve reversible constriction of the airways (bronchospasm) in chronic obstructive lung disease, including patients with:

- Chronic obstructive bronchitis.
- Emphysema.
- Acute bronchospasm due to asthma if combined with inhaled beta-agonists (medicines that work on specific receptors, called beta-receptors, to open up the airways).

BEFORE YOU USE IPVENT 40 HFA:

Do not take IPVENT 40 HFA if you:

- Are allergic (hypersensitive) to ipratropium bromide or other atropine-like substances or any other component of this medicine.
- Are pregnant or breastfeeding.

Safety of **IPVENT 40 HFA** in children has not been proven.

Take special care with IPVENT 40 HFA:

The presence of other medical conditions may affect the use of **IPVENT 40 HFA.** Tell your doctor or pharmacist if you have any of the following conditions as you may require a lower dose or special monitoring:

- Narrow-angle glaucoma, a condition characterised by raised pressure inside the eye associated with pain, blurred vision and red eyes.
- Enlargement of the prostate gland.
- Obstruction of urinary flow due to narrowing of the bladder neck.

- Cystic fibrosis, as you may be more prone to develop adverse events involving your alimentary tract (gut).

Immediate allergic (hypersensitivity) reactions may occur after administration of **IPVENT 40 HFA,** as demonstrated by hives, swelling of the face or limbs, rash, tightness of the chest and swelling of the mouth, throat and lips, and anaphylaxis (acute allergic reaction involving the whole body). You should report such symptoms to your doctor as a matter of urgency.

There have been reports of eye complications when **IPVENT 40 HFA** came into contact with the eyes, such as:

- Mydriasis, a long-continued or excessive dilatation of the pupil of the eye.
- Increased intraocular (inside the eye) pressure.
- Narrow-angle glaucoma, a condition characterised by raised intraocular pressure and complicated by defects in the field of vision.
- Eye pain.

Please follow the instructions under **"HOW TO TAKE IPVENT 40 HFA"** very carefully. You should contact your doctor immediately if you develop eye pain or discomfort, blurred vision, visual halos or coloured images, in association with red eyes.

Combined use of **IPVENT 40 HFA** with medication that also causes dilation of the airways (bronchodilatation), such as medicines known as beta-agonists or xanthines, may intensify the bronchodilatory effects of **IPVENT 40 HFA.**

Using IPVENT 40 HFA with food and drink:

IPVENT 40 HFA can be administered without regard to meals.

Use in pregnancy and breastfeeding:

Safety and efficacy of **IPVENT 40 HFA** in pregnancy and breastfeeding has not been established.

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

Driving and using machinery:

IPVENT 40 HFA is unlikely to produce an effect. However, if you experience dizziness as a side-effect, you should refrain from driving a car or operating machinery where dizziness may lead to accidents.

Taking other medicines with IPVENT 40 HFA?

See **"BEFORE YOU TAKE IPVENT 40 HFA"** regarding the use of **IPVENT 40 HFA** with other medicines that dilate the airways. If you are taking other medicines on a regular basis, including complementary or traditional medicines, use of **IPVENT 40 HFA** with other medicines may cause undesirable interactions. Please consult your doctor or pharmacist or other healthcare professional for advice.

HOW TO TAKE IPVENT 40 HFA:

Always take IPVENT 40 HFA exactly as your doctor has instructed you.

You should check with your doctor or pharmacist if you are unsure.

The usual dose in adults is 1 metered dose (puff) four times daily. A total dose of 8 puffs per day should not be exceeded. If you need to increase the dose, please consult your doctor, because this may suggest that other additional treatment is required.

Only use the CIPLA **IPVENT 40 HFA** mouthpiece to administer this medicine.

Use in children:

The use of **IPVENT 40 HFA** is contra-indicated in children as safety has not been established.

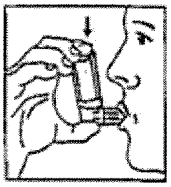
Instructions for use:

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

Depress the valve twice before the apparatus is used for the first time.

Before each use the following rules should be observed:

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.


Fig 1

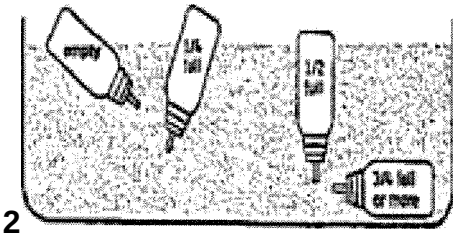
5. Breathe in as deeply as possible and press the base of the canister firmly at the same time - this releases one metered dose. Hold your breath for a few seconds, then remove the mouthpiece from your mouth and breathe out. The same action should be repeated for a second inhalation.
6. Replace the protective 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).

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.

Fig. 2



If you take more IPVENT 40 HFA than you should:

In the event of an overdosage, or if someone else has taken your medicine by mistake, you, or this other person, may experience side-effects such as those listed below. The most common side-effects from overdosage include dry mouth, visual disturbances and rapid heart rate (palpitations). In the event of overdosage, consult your doctor or pharmacist immediately. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take IPVENT 40 HFA:

Always take **IPVENT 40 HFA** as prescribed. If you miss a dose of this medicine, take it as soon as possible. However, if you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to compensate for the forgotten individual dose.

POSSIBLE SIDE-EFFECTS:

IPVENT 40 HFA may have unintended or undesirable effects. Not all side-effects reported for this medicine are included in this leaflet.

Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

The most serious side-effects of **IPVENT 40 HFA** include:

- Allergic reactions, which may present with swelling of the lips, face, tongue or throat, hives or skin rash, and difficulty breathing. You should report such symptoms to your doctor as a matter of urgency.
- Difficulty breathing due to swelling of the throat or constriction of the airways. If you experience difficulty breathing, you should report to your doctor immediately.
- Eye complications if **IPVENT 40 HFA** comes into direct contact with the eyes. Please see **"Take special care with IPVENT 40 HFA".**
- Vomiting, loss of appetite, bloated stomach, stomach pain or cramping and inability to pass stool as this may indicate a condition known as paralytic ileus.

You should check with your doctor or pharmacist as soon as possible if you notice any of the following side-effects:

- Visual disturbances, sudden pain in the eye, blurred vision or other changes in vision, or burning eyes.
- Palpitations or increased heart rate.
- Difficult urination.

You should check with your doctor if any of the following side-effects continue or become bothersome:

- Headache, nervousness, trembling and dizziness.
- Cough.
- Local irritation of the mouth or throat.

- Dryness of the mouth or unpleasant taste.
- Nausea or constipation.
- Skin rash, including a skin rash accompanied by itching, and increased sweating.

Not all side-effects reported for this medicine are included in this leaflet.

Please tell your doctor or pharmacist of any undesirable effects you think may be due to **IPVENT 40 HFA,** especially if not mentioned in this leaflet.

STORAGE AND DISPOSING OF IPVENT 40 HFA:

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.

Do not use after the expiry date stated on the packaging material.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems, for example toilets.

PRESENTATION OF IPVENT 40 HFA:

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

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

IDENTIFICATION OF IPVENT 40 HFA:

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

REGISTRATION NUMBER:

43/10.2.1/0544

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

CIPLA MEDPRO (PTY) LTD
Rosen Heights,
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DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET:

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