FORMOTEROL FUMARATE HFA		
1.3 South African labelling and packaging		
Document	1.3.2	Proposed Patient Information Leaflet

Patient Information Leaflet

Information for the Patient about

FORATEC HFA (metered dose inhaler)

Read all of this leaflet carefully before you start taking 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:

S2

PROPRIETARY NAME AND DOSAGE FORM:

FORATEC HFA (metered dose inhaler)

WHAT FORATEC HFA CONTAINS:

The active substance is formoterol fumarate.

FORATEC HFA contains 12 mcg of formoterol fumarate.

The other inactive ingredients are lecithin, absolute alcohol and tetrafluoroethane (HFA-134a).

WHAT FORATEC HFA IS USED FOR:

FORATEC HFA belongs to a group of medicines called bronchodilators. It works by blocking the release of histamines and leukotrienes in human lung tissue, which cause bronchoconstriction in the lung tissue. FORATEC HFA is used for prophylaxis and treatment of bronchoconstriction in patients with reversible obstructive airway disease, such as bronchial asthma and chronic bronchitis, with or without emphysema. FORATEC HFA is also used in Prophylaxis of bronchospasm induced by inhaled allergen, non- specific irritants or exercise challenge.

BEFORE YOU TAKE FORATEC HFA:

Do not take FORATEC HFA if you:

Have shown hypersensitivity to formoterol or other adrenergic stimulants

Have tachycardia,

Have third degree atrioventricular block,

Have idiopathic subvalvular aortic stenosis,

Have hypertrophic obstructive cardiomyopathy,

Have prolonged Q-T interval (Q-Tc >0,44 second)eg congenital or drug induced (See Interactions),

Have thyrotoxicosis.

Are a child under the age of 6 years, as safety has not been established.

Are pregnant and/or a lactating woman

Take special care with FORATEC HFA:

Tell your doctor if you have any of the following as you may then require a lower dose or special monitoring: drink substantial amounts of alcohol and/or have a history of liver disease.

If you are taking the following in addition to FORATEC HFA please tell your doctor or pharmacist. In certain cases, your doctor may want to change the dose, or other precautions may be necessary:
Quinidine, disopyramide, procainamide, phenothiazines, antihistamines and tricyclic antidepressants may increase the risk of ventricular arrhythmias
Xanthine derivatives, corticosteroids or diuretics may potentiate the hypokalaemic effect of β2-agonists.

Taking FORATEC HFA with food and drink:

See 'HOW TO TAKE FORATEC HFA'.

Use in pregnancy and breast feeding:

Do not take FORATEC HFA if you are pregnant or breast feeding. If you are pregnant or breast feeding your baby while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Use in children:

It is not recommended for children as the safety and efficacy has not been established.

Taking other medicines with FORATEC HFA?

See "BEFORE YOU TAKE FORATEC HFA"
If you are taking other medicines on a regular basis, use of this medicine with other medicines may cause undesirable interactions. Please consult your doctor or pharmacist.

HOW TO TAKE FORATEC HFA:

Always take FORATEC HFA exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
Regular maintenance and prophylactic therapy

One puff of 12 g taken twice daily, in the morning and in the evening.In the exceptional case where an acute attack occurs, one or two additional puffs may be taken. In such cases the maximum daily dose is
48 g or 4 puffs

If you take more FORATEC HFA than you should:

In the event of an overdosage (if you take too much), or

If someone else has taken your medicine by mistake, you, or this other person, will require general supportive measures.

Contact your doctor or pharmacist immediately. If neither is available, seek help at the nearest hospital or poison control centre.

Take FORATEC HFA as prescribed. If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, 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:

What undesirable effects may FORATEC HFA have?

FORATEC HFA can have side-effects. As with any medicine, FORATEC HFA may have unintended or undesirable effects. Although not all the side-effects may occur, if they do occur, they may go away during treatment as your body adjusts to the medicine. Check with your doctor immediately if the side-effects become or go to the casualty department at your nearest as you may need urgent medical attention.

Fatigue, fever and flu-like symptoms, Palpitations, Tremor, headache, dizziness, Upper respiratory tract symptoms, exacerbation of asthma and dyspnoea

The following have been reported less frequently: problems with sinusitis, dry mouth and nausea.

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.

STORAGE AND DISPOSING OF FORATEC HFA:

Store this medicine out of reach of children. Store in a dry place at or below 25 °C. Protect from excessive heat, freezing and moisture. The canister is pressurised. It should not be broken, punctured or burnt, even when apparently empty. 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 FORATEC HFA:

FORATEC HFA: A pressurised aluminium canister which delivers 12 g formoterol fumarate with each actuation. Each canister provides 120 metered dose inhalations.

IDENTIFICATION OF FORATEC HFA:

FORATEC HFA: White homogenous suspension aerosol for inhalation, in propellant HFA-134a, supplied in a pressurized container.

REGISTRATION NUMBER:

40/10.2.1/0413

NAME AND ADDRESS OF REGISTRATION HOLDER:

CIPLA MEDPRO (PTY) LTD

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