

For the use of registered medical practitioner or a hospital or a laboratory

# FORATEC INHALER

Formoterol Fumarate Inhaler

## Composition

Each actuation delivers :

- Formoterol Fumarate ..... 12 mcg
- Appropriate overages added

## Description

- FORMOTEROL FUMARATE a long acting  $\beta_2$ -adrenoreceptor agonist, produces dose proportional bronchodilation in patients with obstructive airway disease with a reversible component. Significant effect occurs within minutes of inhalation of a therapeutic FORMOTEROL dose and persists for approximately 12 hours.

## Indications and usage

FORMOTEROL FUMARATE is indicated for maintenance therapy and prophylaxis of reversible obstructive airway disease, including intrinsic and exercise induced asthma and COPD in patients 5 years of age and above.

## Dosage and Administration

*Adults*

1-2 puffs twice daily

If needed, 1 or 2 additional doses of 12mcg/day on no more than 2 days/week.

*Pediatric patients 5 years of age and above*

1-2 puffs twice daily

## Contraindications

Hypersensitivity to any component of this product.

## Warnings and Precautions

- FORMOTEROL FUMARATE should not be initiated in patients with worsening or deteriorating asthma.

- FORMOTEROL is not a substitute for inhaled or oral corticosteroids.
- As with other  $\beta_2$  agonists, formoterol can produce paradoxical bronchospasm that can be life threatening. In such cases, the drug must be discontinued immediately and alternative therapy started.
- FORMOTEROL should be used with caution in patients with cardiovascular disorders especially coronary insufficiency, cardiac arrhythmias and hypertension.
- FORMOTEROL may produce significant hypokalemia, which is usually transient.

### Drug interactions

- Concomitant treatment with xanthine derivatives, steroids or diuretics may potentiate the hypokalemic effects of  $\beta_2$  agonists.
- $\beta$ -blockers are known to block the therapeutic effects of  $\beta_2$  agonists. Hence they have to be used with extreme caution when a combination is mandatory.
- Special populations  
Pregnancy and lactation: FORMOTEROL should be used in only when the potential benefit justifies the potential risk to the fetus. There are no well-controlled human studies of its use in nursing mothers.

### Storage

Store below 30°C and protect from direct sunlight.  
Do not freeze.

### Presentation

Foratec Inhaler

120 metered doses