

# **Bexitrol®**

Inhaler

## **Description**

Salmeterol Xinafoate INN, the active ingredient of Bexitrol Inhaler, is a selective, long acting  $\beta_2$  agonist used in the treatment of asthma and other forms of diffuse airways obstruction. Bexitrol Inhaler is a metered dose aerosol unit containing a micro-crystalline suspension of Salmeterol in a mixture of propellant with lecithin.

## **Indications**

Bexitrol (Salmeterol) is a long acting  $\beta_2$  agonist which is considerably more potent, selective and long acting compared with traditionally used bronchodilators. Bexitrol protects against asthma induced by histamine or methacholine for a period of at least 12 hours in adults and children. Furthermore, long acting  $\beta_2$  agonist show a more than 4 fold greater potency than short acting agents (for example, Salbutamol) against histamine induced bronchoconstriction. Bexitrol has the potential to improve the treatment of patients with asthma; the drug provides prolonged bronchodilation and decrease asthma symptoms and the need for short acting  $\beta_2$  agonist, independently of concomitant steroid use. Studies have consistently reported improved control of nocturnal asthma with long acting  $\beta_2$  agonist compared with other anti-asthma drugs. Bexitrol is indicated for the long term regular treatment of reversible airways obstruction (including nocturnal and exercise induced asthma) and chronic bronchitis. In paediatric asthma, the use of Bexitrol may avoid exposure of children to Theophylline or high dose corticosteroids, with their attendant risks.

## **Dosage and Administration**

The recommended dose is 50  $\mu\text{g}$  (2 puffs) twice daily, although in severe disease the dose may be increased to 100  $\mu\text{g}$  twice daily. The drug should not be used on an 'as required' basis, although on account of its efficacy in nocturnal and exercise induced asthma, single dose administration may be considered as a treatment option.

## **Contraindications**

Patients with thyrotoxicosis. Special caution should be exercised in patients with cardiac problems predisposing to arrhythmias. The drug is ineffective in patients taking non-selective  $\beta$  blocking drugs.

## **Precautions**

Bronchodilators should not be the only or the main treatment in patients with severe or unstable asthma. Severe asthma requires regular medical assessment, including lung function testing, as patients are at risk of severe attack or even death. Physicians should consider using oral corticosteroid therapy and/or the maximum recommended dose of inhaled corticosteroid in these patients. Increasing use of bronchodilators, in particular short acting inhaled  $\beta_2$  agonist to relieve symptoms indicates deterioration of asthma control. If patients find that short acting bronchodilator treatment becomes less effective or they need more inhalation than usual, medical attention must be sought. In this situation patients should be reassessed and consideration given to the need for increased anti-inflammatory therapy (e.g., higher doses of inhaled corticosteroid or a course of oral corticosteroids). Severe exacerbation of asthma must be treated in the normal way. Salmeterol inhaler is not designed to relieve acute asthmatic symptoms, for which an inhaled short acting bronchodilator is required. Patients should be advised to have such rescue medication available. Potentially serious hypokalaemia may result from  $\beta_2$  agonist therapy. Particular caution is advised in acute severe asthma as this effect may be potentiated by concomitant treatment with xanthine derivatives, steroids and diuretics. It is recommended that serum potassium levels are monitored in such situations.

## **Side Effects**

No severe irreversible adverse effect is known although systemic  $\beta_2$  agonist effects of Salmeterol may last up to 12 hours. Inhaled dose of Salmeterol up to 400  $\mu\text{g}$  given to healthy volunteers produced significant systemic side effects, the majority of which were pharmacologically predictable. Response observed with 100  $\mu\text{g}$  Salmeterol were similar to those observed with 400  $\mu\text{g}$  Salmeterol. Hypokalaemia, tremor and palpitations may all occur but only at doses of Salmeterol exceeding that recommended.

## **Commercial Pack**

Bexitrol<sup>®</sup> Inhaler : Each canister contains 200 metered doses, each containing Salmeterol Xinafoate INN equivalent to 25  $\mu\text{g}$  Salmeterol.