

AstraZeneca India receives marketing approval for Symbicort 320

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AstraZeneca India receives marketing approval for Symbicort 320 Symbicort 320 mcg is a fixed-dose combination drug comprising budesonide and formoterol fumarate dehydrate delivered through a special device.



AstraZeneca Pharma India Limited (AstraZeneca India), an international biopharmaceutical company has received marketing authorisation from the Drug Controller General of India (DCGI) for Symbicort 20 mcg. Symbicort 320 mcg is a fixed-dose combination drug comprising budesonide and formoterol fumarate dehydrate delivered through a special device. It is indicated for treatment of severe Asthma and for patients with moderate to severe COPD with frequent symptoms and a history of exacerbations.

Symbicort is approved for use in 91 countries for the treatment of Asthma and COPD. Results from AstraZeneca's two major clinical studies have shown that the addition of formoterol to budesonide improved asthma symptoms and lung function, and reduced exacerbation. Similarly, in two 12-month studies in patients with COPD, Symbicort was superior to placebo, formoterol and budesonide regarding lung function and showed a significant reduction in the exacerbation rate compared with placebo and formoterol.

Dr. Anilda D'souza, Head –Medical Affairs & Regulatory, AstraZeneca India said, "Asthma and COPD are common and major causes of chronic morbidity impacting millions of patients in India. It is often not well controlled by existing treatments. AstraZeneca India is pleased to bring Symbicort 320 mcg, which will offer physicians and patients another treatment option for severe asthma and for moderate to severe COPD, where high dosage is required."

Asthma is a common and chronic condition that affects the lungs' airways. Inflammation and narrowing of the airways may cause wheezing, breathlessness, chest tightness and coughing. Symbicort, which is in the form of an inhalation powder, consists of a steroid and a long-acting beta agonist. The steroid component reduces irritation and inflammation and the beta agonist relaxes smooth muscle in the lungs and makes the airways wider, thereby decreasing symptoms.