



**UNICHEM
LABORATORIES LTD.**

Fax No : 91 (22) 2678 4391 / 5198
Tel. No. : 91 (22) 66888333
Website : <http://www.unichemlabs.com>
CIN : L99999MH1962PLC012451.

Registered & Corporate Office : Unichem Bhavan, Prabhat Estate, S. V. Road, Jogeshwari (West), Mumbai-400102, INDIA.

UNICHEM LABORATORIES LIMITED

Press Release

Mumbai, Friday October 09, 2015

Unichem Laboratories receives ANDA approval from USFDA for MONTELUKAST SODIUM TABLETS

Unichem Laboratories Limited is pleased to announce that it has received ANDA approval from the United States Food and Drug Administration (U.S. FDA) for Montelukast Sodium *Tablets*.

Montelukast Sodium *Tablets* 10mg are therapeutically equivalent to Singulair *Tablets* 10mg of Merck Sharp & Dohme Corp.

Montelukast is a leukotriene receptor antagonist (LTRA) which is indicated for:

- Prophylaxis and chronic treatment of asthma in adults and adolescents patients > 15 years age
- Prevention of exercise-induced bronchoconstriction (EIB) adults and adolescents patients > 15 years age
- Relief of symptoms of allergic rhinitis in adults and adolescents patients > 15 years age

The product will be commercialized from Unichem's Goa plant.

Unichem Laboratories Limited now has total of 19 ANDA approvals (Including 3 Tentative Approvals) from USFDA.





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About Unichem Laboratories Limited

Unichem Laboratories Limited is an international, integrated, specialty pharmaceutical company. It manufactures and markets a large basket of pharmaceutical formulations as branded generics as well as generics in India and several other markets across the world. In India, the company is a leader in niche therapy areas of cardiology, neurology, orthopedics and anti-infectives. The company has strong skills in product development, process chemistry and manufacturing of complex API as well as dosage forms. More information about the company can be found at www.unichemlabs.com

For more information please contact:

Ms. Neema Thakore

Ph: +91-22-66888 404

E-mail: neema.thakore@unichemlabs.com

Mr. Rakesh Parikh/ Mr. Monish Shah

Ph: +91-22-66888 414

Ph: +91-22-66888 509

E-mail: rparikh@unichemlabs.com

monish.shah@unichemlabs.com

Disclaimer: This press release includes forward-looking statements. We have based these forward-looking statements on our current expectations and projections about future events. Such statements involve known and unknown risks, uncertainties and other factors that may cause actual results to differ materially. Such factors include, but are not limited to, changes in local and global economic conditions, our ability to successfully implement our strategy, the market acceptance of and demand for our products, our growth and expansion, technological change and our exposure to market risks. By their nature, these expectations and projections are only estimates and could be materially different from actual results in the future.

