



UNICHEM LABORATORIES LIMITED

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Press Release

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Unichem Laboratories receives Final ANDA approval from USFDA for Irbesartan Tablets USP

Unichem Laboratories Limited is pleased to announce that it has received Final ANDA approval (Tentative Approval was received earlier) from the United States Food and Drug Administration (USFDA) for Irbesartan Tablets USP.

Irbesartan Tablets USP 75mg, 150mg and 300mg are therapeutically equivalent to Avapro Tablets, 75mg, 150mg and 300 mg of Sanofi-aventis U.S.LLC.

Irbesartan is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents. Irbesartan is also indicated for the treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (>300 mg/day) in patients with type 2 diabetes and hypertension. In this population, Irbesartan reduces the rate of progression of nephropathy as measured by the occurrence of doubling of serum creatinine or end-stage renal disease (need for dialysis or renal transplantation).

The product will be commercialized from Unichem's Ghaziabad plant. Active Pharmaceutical Ingredient will also be made in house at Pithampur API Plant.



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

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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.*