A new oral testosterone undecanoate formulation.

Testosterone undecanoate has been available on the market for more than 20 years. This testosterone ester is used worldwide for oral treatment of male hypogonadism. So far, testosterone undecanoate has been dissolved in oleic acid, leading to inconvenient storage conditions. It will now be available in a new formulation with castor oil and propylene glycol laurate instead of oleic acid, thus improving storage conditions markedly (stable at room temperature for approximately 3 years). Pharmacokinetic and pharmacodynamic studies have demonstrated bioequivalence of the old and the new formulation of testosterone undecanoate. Therefore, the results of studies that were performed with the old formulation can be transferred to the clinical use of the new formulation. Controlled studies have shown its efficacy in the treatment of symptoms associated with reduced serum testosterone levels. In these cases testosterone undecanoate improves bone mineral density, quality of life, muscle mass, libido and mood. Further studies will help evaluate the efficacy and safety of the new formulation in the treatment of elderly men with late-onset hypogonadism.