



First combination of NSAID and proton pump inhibitor approved

The decentralised registration procedure for the combination product ketoprofen and omeprazole has been finalised with a positive assessment. Ketoprofen is a NSAID (Non Steroidal Anti-Inflammatory Drug) for the treatment of rheumatic disorders and omeprazole is an acid reducing proton pump inhibitor (PPI). Both substances are well known and broadly used. Co-prescription of NSAIDs and PPIs as single substances represent a market of around SEK 3 billion in Europe.

"We are very pleased to announce registration approval for this first combination product of a NSAID and a PPI. This product prevents gastrointestinal side effects from use of NSAIDs. The once daily administration increases patient compliance", said Anders Lönner, Meda's CEO.

The product is patent protected and uses a capsule formulation for ketoprofen sustained-release granulate and omeprazole enteric-coated granulate. The product was filed for registration using the decentralised procedure on certain key European markets; Italy, Spain, Germany, Portugal, Poland and the UK. The decentralised part of the procedure has now been finalised, and it's expected that the decision of the reference authority in the UK will be adopted in most of these countries. Thereafter, national phases will follow that include local adoption of labelling texts and summary of products characteristics and reimbursement / pricing approval. This is expected to take nine to twelve months which would enable launch during fourth quarter 2009. Registration processes in other European countries will start in parallel.

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