



25 April 2013
EMA/CHMP/132029/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Nuedexta

Dextromethorphan and quinidine

On 25 April 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Nuedexta, 15 mg / 9 mg, 23 mg / 9 mg hard capsule intended for the treatment of pseudobulbar affect, a medical condition in which patients experience sudden and uncontrollable bouts of laughing or crying unrelated or disproportionate to their emotional state. The applicant for this medicinal product is Jenson Pharmaceutical Services Ltd. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substances of Nuedexta are dextromethorphan hydrobromide and quinidine sulfate. Dextromethorphan influences the glutamate neurotransmitting pathways that regulate emotional expression, while quinidine increases dextromethorphan blood levels by inhibiting its metabolism.

The benefits with Nuedexta are its ability to reduce the number of episodes of uncontrollable emotional expression. The most common side effects are dizziness, somnolence, headache, diarrhoea and fatigue.

A pharmacovigilance plan for Nuedexta will be implemented as part of the marketing authorisation.

The approved indication is: Nuedexta is indicated for the symptomatic treatment of pseudobulbar affect (PBA) in adults (see section 4.4). Efficacy has only been studied in patients with underlying Amyotrophic Lateral Sclerosis or Multiple Sclerosis (see section 5.1).

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.



The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Nuedexta and therefore recommends the granting of the marketing authorisation.

Medicinal product no longer authorised