19 November 2015
EMA/CHMP/759419/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Wakix

pitolisant

On 19 November 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Wakix, intended for the treatment of narcolepsy with or without cataplexy. Wakix was designated as an orphan medicinal product on 10 July 2007. The applicant for this medicinal product is Bioprojet Pharma.

Wakix will be available as 4.5 and 18 mg film-coated tablets. The active substance of Wakix is pitolisant, an antagonist/inverse agonist of the histamine H3 receptor (ATC code: N07XX11). It works by enhancing the histaminergic transmissions in the brain.

The benefits with Wakix are its ability to decrease daytime somnolence and cataplexy rate. The most common side effects are headache, insomnia and nausea.

The full indication is: “Wakix is indicated in adults for the treatment of narcolepsy with or without cataplexy". It is proposed that Wakix be prescribed by physicians experienced in the treatment of sleep disorders.

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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact