18 December 2014
EMA/CHMP/756988/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Mysimba

naltrexone/bupropion

On 18 December 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Mysimba, 8 mg / 90 mg, prolonged-release tablet, intended as an adjunct to a reduced-calorie diet and increased physical activity, for the management of weight in adult patients.

The applicant for this medicinal product is Orexigen Therapeutics Ireland Limited. 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 Mysimba are naltrexone and bupropion, centrally acting anti-obesity products, ATC code A08AA. Naltrexone is a mu-opioid antagonist and bupropion is a norepinephrine and dopamine reuptake inhibitor. Both compounds affect key circuitry in two areas of the brain to influence eating behaviour. The first area is the arcuate nucleus of the hypothalamus, an area of the brain that plays a critical role in the control of food intake and energy expenditure. The second is the mesolimbic dopaminergic reward system, a region of the brain that is important for processing the rewarding aspects of food and food related stimuli.

The main benefit of Mysimba is the achievement of a clinically relevant weight loss.

In clinical studies, the most frequent adverse reactions observed with Mysimba were gastrointestinal adverse reactions (nausea, constipation, vomiting, dizziness, and dry mouth).

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

The approved indication is " Mysimba is indicated as an adjunct to a reduced-calorie diet and increased physical activity, for the management of weight in adult patients (≥18 years) with an initial Body Mass Index (BMI) of

[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.

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- ≥ 30 kg/m² (obese), or
- ≥ 27 kg/m² to < 30 kg/m² (overweight) in the presence of one or more weight-related co-morbidities (e.g., type 2 diabetes, dyslipidaemia, or controlled hypertension)".

Treatment with Mysimba should be discontinued after 16 weeks if patients have not lost at least 5% of their initial body weight."

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.

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