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Press Office

Press release

Mysimba recommended for approval in weight management in adults

Medicine to be used in addition to reduced-calorie diet and physical activity

The European Medicines Agency (EMA) has recommended granting a marketing authorisation for Mysimba (naltrexone / bupropion) for weight management of overweight or obese adults. The medicine is recommended for use in addition to a reduced-calorie diet and physical activity.

The medicine, which will only be available on prescription, provides a treatment option for adults with a body mass index (BMI) of 30 kg/m^2 or greater (obese), or a BMI of 27 kg/m^2 to <30 kg/m^2 (overweight) in the presence of one or more complications related to their weight, such as type 2 diabetes, high cholesterol or high blood pressure.

Being overweight or obese is a major risk factor for a number of chronic diseases, including diabetes and cardiovascular disease. Currently, pharmacological therapies for weight management are limited.

Mysimba is a prolonged release tablet to be taken orally. It is a combination of two active substances (bupropion and naltrexone) already approved for use in the European Union (EU) in other indications. These active substances affect two key areas of the brain responsible for the control of food intake and energy expenditure, and for the reward pathways associated with eating food.

The effectiveness of Mysimba was assessed in four pivotal studies that included obese and overweight patients with and without weight-related conditions treated for one year. All patients enrolled in trials were required to change their lifestyle to incorporate a reduced-calorie diet and regular physical activity. Across these studies, more patients treated with Mysimba achieved clinically-relevant weight loss than patients treated with placebo.

The main safety and tolerability concerns identified with Mysimba were related to central nervous system and gastrointestinal adverse events, and uncertainties with regard to cardiovascular outcomes in the longer term. Interim results from an ongoing cardiovascular outcome trial were reassuring in terms of risk of serious cardiovascular disease related to treatment with Mysimba. A second study is planned in order to continue monitoring longer-term cardiovascular safety with the medicine.

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The CHMP recommended that patients started on Mysimba should be evaluated after 16 weeks. If a patient has not lost at least five per cent of their initial body weight by this time, treatment with Mysimba should be stopped. The product information for this medicine provides advice on the safe use of the product.

The opinion adopted by the CHMP at its December 2014 meeting is an intermediary step on Mysimba's path to patient access. The CHMP opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation. Once a marketing authorisation has been granted, decisions about price and reimbursement will then take place at the level of each Member State considering the potential use of Mysimba in the context of the national health system of that country.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The marketing authorisation applicant for Mysimba is Orexigen Therapeutics Ireland Limited.
3. BMI, which measures body fat based on an individual's weight and height, is used to define the obesity and overweight categories.
4. Bupropion (Zyban) was first approved in 1999 through the Mutual Recognition Procedure (MRP) as an aid in smoking cessation. In 2007, Bupropion (Wellbutrin XR) also underwent the MRP procedure and was approved for the treatment of major depressive episodes. Bupropion is registered in all EU countries with the exception of Bulgaria.
5. For naltrexone, either the originator Nalorex or several generic products are available in most EU Member States.
6. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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