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EMA starts review of weight management medicine Mysimba

EMA has started a review of Mysimba (naltrexone / bupropion), a medicine for weight management in adults who have obesity or are overweight. The medicine is recommended for use in addition to diet and exercise.

The review of Mysimba was prompted by remaining concerns regarding the potential long-term cardiovascular risk (affecting the heart and blood circulation) with Mysimba and its impact on the benefit-risk balance of the medicine.

Uncertainties regarding the long-term effects of Mysimba on the cardiovascular system were noted at the time of Mysimba's authorisation. Two studies evaluating cardiovascular risk with this medicine were stopped before completion, and a third study was therefore required to comply with the conditions of the marketing authorisation.

At the time of the review, the third study to evaluate the potential cardiovascular risk with the medicine had not yet started and EMA's human medicines committee (CHMP) considered study designs proposed by the marketing authorisation holder (MAH) insufficient to investigate long-term cardiovascular safety. In addition, risk minimisation measures proposed by the MAH to mitigate the potential risk in patients receiving long-term treatment with Mysimba were not considered sufficient to overcome the need for a study.

EMA will now assess all available data on the potential long-term cardiovascular safety risk and its impact on the benefit-risk balance of Mysimba in its approved indication and recommend whether the medicine's marketing authorisation in the EU should be amended, suspended or revoked.

More about the medicine

Mysimba is a medicine used along with diet and exercise to help manage weight in adults who have obesity (have a body-mass index - BMI - of 30 or more) or who are overweight (have a BMI between 27 and 30) and have weight-related complications such as diabetes, abnormally high levels of fat in the blood, or high blood pressure. It was granted marketing authorisation on 26 March 2015.

More information about the medicine can be found on the EMA website.

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More about the procedure

The review of Mysimba has been initiated at the request of the European Commission, under Article 20 of Regulation (EC) No 726/2004.

The review is being carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's opinion. The CHMP opinion will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.