

Consumer Update

Feb 2023

Bupropion and the risk of unmasking of Brugada Syndrome

EDA performs label update to include the following:

Special warnings and precautions for use

Brugada syndrome Bupropion may unmask Brugada syndrome, a rare hereditary disease of the cardiac sodium channel with characteristic ECG changes (right bundle branch block and ST segment elevation in right precordial leads), which may lead to cardiac arrest or sudden death. Caution is advised in patients with Brugada syndrome or a family history of cardiac arrest or sudden death.

Background:

Therapeutic indications

Bupropion 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

- * \geq 30 kg/m2 (obese), or
- * ≥ 27 kg/m² to < 30 kg/m² (overweight) in the presence of one or more weight-related comorbidities (e.g., type 2 diabetes, dyslipidaemia, or controlled hypertension) Treatment should be discontinued after 16 weeks if patients have not lost at least 5% of their initial body weight

References: EMA (Click here)