

Statement of Advice:

**naltrexone hydrochloride / bupropion hydrochloride 8mg / 90mg
prolonged-release tablets (Mysimba®) SMC2086**
Orexigen Therapeutics Ireland Limited

6 April 2018

ADVICE: in the absence of a submission from the holder of the marketing authorisation

naltrexone / bupropion (Mysimba®) is not recommended for use within NHS Scotland.

Indication under review: 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

- ≥ 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)

The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Chairman
Scottish Medicines Consortium