MYSIMBA®▼

naltrexone HCl/bupropion HCl
8mg/90mg Prolonged-Release Tablets

PHYSICIAN PRESCRIBING CHECKLIST

OREXIGEN®

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Mysimba®(naltrexone/bupropion)

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) ≥ 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 (see Section 5.1).

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Patient details

Male ☐ Female ☐ *If female, check whether there is any possibility of pregnancy as Mysimba must not be taken during pregnancy or when breast-feeding*

Age (yrs) ☐ Weight (kg) ☐ Height (m) ☐ BMI (kg/m^2) ☐

Hypertension ☐ Hypercholesterolaemia ☐ Other CHD risk factor ☐

Smoking ☐ Low HDL cholesterol ☐

Diabetes ☐ Hypertriglyceridaemia ☐ Current BP (mmHg) ☐/☐

Does the patient have:	**NO**	**YES**
Uncontrolled hypertension?	☐	☐
Current seizure disorder, history of seizures or known CNS tumour?	☐	☐
Current or previous diagnosis of bulimia or anorexia nervosa?	☐	☐
Current dependence on chronic opioids or opiate agonists?	☐	☐
Ongoing acute alcohol, benzodiazepine or opioid withdrawal treatment?	☐	☐
Current treatment with bupropion or naltrexone?	☐	☐
History of bipolar disorder?	☐	☐
Treatment with a MAOI within the last 14 days?	☐	☐
Severe hepatic impairment or end stage renal failure?	☐	☐

Contraindications DO NOT PRESCRIBE Mysimba if you tick any of these boxes

Does the patient have:	**NO**	**YES**
Moderate or severe renal insufficiency? ***(If diabetic or elderly patient or at risk for renal insufficiency, assess eGFR prior to initiating Mysimba therapy)***	☐	☐
Moderate hepatic impairment?	☐	☐
Controlled hypertension?	☐	☐
Angina or recent history of myocardial infarction?	☐	☐
History of mania?	☐	☐
Suicidal ideation or history of attempted suicide (particularly in young people)?	☐	☐
Depression?	☐	☐
Risk factors for seizures (such as: history of head trauma, episodes of hypoglycaemia from diabetes treatment, concomitant medication that could lower the seizure threshold such as: antipsychotics, antidepressants, antimalarials, tramadol, theophylline, systemic steroids, quinolones or sedating antihistamines?)	☐	☐

Patients with any of these factors are at an increased risk of adverse reactions. Treatment should only be initiated or maintained after full evaluation of the possible benefits and risks and review of section 4.4 of the SmPC

Treat with Mysimba? Yes ☐ No ☐ **Date** dd/mm/yyyy

Discontinue treatment if there are concerns with the safety or tolerability of ongoing treatment

▼This medicinal product is subject to additional monitoring. Please report **suspected adverse drug reactions (ADRs)** to the MHRA through the Yellow Card scheme, via the Yellow Card website www.mhra.gov.uk/yellowcard, the free Yellow Card app available from the Apple App Store or Google Play Store, and also some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals. Alternatively you can report a suspected adverse drug reactions to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours. Adverse events should also be reported to Orexigen®: +44 20 3966 0116 or currax.mi@primevigilance.com. When reporting please provide as much information as possible. By reporting adverse drug reactions, you can help provide more information on the safety of this medicine.

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Please consult the Summary of Product Characteristics (SmPC) before prescribing.
The SmPC for Mysimba may be found at https://www.medicines.org.uk/emc