

PHYSICIAN PRESCRIBING CHECKLIST

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) $\geq 30 \text{ kg/m}^2$ (obese), or $\geq 27 \text{ kg/m}^2$ to $< 30 \text{ kg/m}^2$ (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 of the SmPC).

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

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/m²)

Hypertension Hypercholesterolaemia Other CHD risk factor

Smoking Low HDL cholesterol

Diabetes Hypertriglyceridaemia Current BP (mmHg)

Does the patient have:

NO YES

Uncontrolled hypertension?	<input type="checkbox"/>	<input type="checkbox"/>
Current seizure disorder, history of seizures or known CNS tumour?	<input type="checkbox"/>	<input type="checkbox"/>
Current or previous diagnosis of bulimia or anorexia nervosa?	<input type="checkbox"/>	<input type="checkbox"/>
Current dependence on chronic opioids or opiate agonists?	<input type="checkbox"/>	<input type="checkbox"/>
Ongoing acute alcohol, benzodiazepine or opioid withdrawal treatment?	<input type="checkbox"/>	<input type="checkbox"/>
Current treatment with bupropion or naltrexone?	<input type="checkbox"/>	<input type="checkbox"/>
History of bipolar disorder?	<input type="checkbox"/>	<input type="checkbox"/>
Treatment with a MAOI within the last 14 days?	<input type="checkbox"/>	<input type="checkbox"/>
Severe hepatic impairment or end stage renal failure?	<input type="checkbox"/>	<input type="checkbox"/>

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

Does the patient have:

NO YES

Moderate or severe renal insufficiency <i>(If diabetic or elderly or at risk for renal insufficiency, assess eGFR prior to initiating Mysimba therapy)</i>	<input type="checkbox"/>	<input type="checkbox"/>
Mild or moderate hepatic impairment? Mysimba is not recommended in patients with moderate hepatic impairment	<input type="checkbox"/>	<input type="checkbox"/>
Controlled hypertension?	<input type="checkbox"/>	<input type="checkbox"/>
Active coronary artery disease or history of cerebrovascular disease?	<input type="checkbox"/>	<input type="checkbox"/>
History of mania?	<input type="checkbox"/>	<input type="checkbox"/>
Suicidal ideation or history of attempted suicide?	<input type="checkbox"/>	<input type="checkbox"/>
Depression?	<input type="checkbox"/>	<input type="checkbox"/>
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?)	<input type="checkbox"/>	<input type="checkbox"/>
A situation requiring intermittent opioid or opioid-like medicinal products?	<input type="checkbox"/>	<input type="checkbox"/>

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. Further information is available to Prescribers who are advised to refer to SmPC section 4.2 Posology and method of administration and Section 4.4 Special warnings and precautions for use.

Treat with Mysimba? Yes No

Date

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

This medicinal product is subject to additional monitoring. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie. Adverse events should also be reported to Orexigen®: 1-800-902-210 or Mysimba@druginfo.com.



Please consult the Summary of Product Characteristics (SmPC) before prescribing. The SmPC for Mysimba may be found at <http://www.medicines.ie>

