# 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) ≥ 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 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? | ☐ | ☐ |
| 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 or at risk for renal insufficiency, assess eGFR prior to initiating Mysimba therapy)*** | ☐ | ☐ |
| Mild or moderate hepatic impairment? Mysimba is not recommended in patients with moderate hepatic impairment | ☐ | ☐ |
| Controlled hypertension? | ☐ | ☐ |
| Active coronary artery disease or history of cerebrovascular disease? | ☐ | ☐ |
| History of mania? | ☐ | ☐ |
| Suicidal ideation or history of attempted suicide? | ☐ | ☐ |
| 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?) | ☐ | ☐ |
| A situation requiring intermittent opioid or opioid-like medicinal products? | ☐ | ☐ |

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** 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. 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®: +44 20 3966 0116 or currax.mi@primevigilance.com.