Physician Prescribing Checklist before and during treatment with Mysimba (naltrexone/bupropion)

Initial assessment ☐ **16-Week assessment** ☐ **Annual assessment** ☐ **Assessment Date** ____/____/_____
dd mm yyyy

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** (patients with obesity), or
- An initial BMI **≥ 27 kg/m²** (overweight) in the presence of one or more **weight-related co-morbidities** (e.g., type 2 diabetes, dyslipidaemia, or controlled hypertension).

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.* ☐/☐ Current BP (mmHg)

☐ Age ☐ Weight (kg) ☐ Height (m) ☐ BMI (kg/m²) ☐ Pulse (bpm)

☐ Hypertension ☐ Diabetes ☐ Dyslipidaemia ☐ Depression ☐ Smoking

Contraindications

DO NOT PRESCRIBE if the patient has any of these factors:

- ☐ Uncontrolled hypertension
- ☐ Severe hepatic impairment or end stage renal failure
- ☐ Current seizure disorder, history of seizures or known CNS tumour
- ☐ Ongoing acute alcohol or benzodiazepine or opioid withdrawal
- ☐ Current or previous diagnosis of bulimia or anorexia nervosa
- ☐ History of bipolar disorder

Currently treated with:

- ☐ Bupropion or naltrexone
- ☐ Opioid agonists
- ☐ Monoamine oxidase inhibitors (MAOI) within the last 14 days

Increased risk of adverse reaction

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

- ☐ Controlled hypertension (potential increased blood pressure risk)
- ☐ Angina or recent history of myocardial infarction
- ☐ Mild hepatic impairment (**dose adjustment necessary**), moderate hepatic impairment (**treatment not recommended**)
- ☐ Moderate or severe renal impairment **(dose adjustment necessary).** *If diabetic or elderly patient or at risk for renal insufficiency, assess eGFR prior to initiating treatment)*
- ☐ Depression or history of suicidal thoughts/suicidal attempt
- ☐ History of mania
- ☐ 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*

Do not initiate/continue treatment if there are concerns with the safety or tolerability of Mysimba treatment. Additionally, treatment with Mysimba should be discontinued after 16 weeks or at the annual assessment if the patient has not lost or maintained a loss of at least 5% of their initial body weight (Section 4.1 and 4.2 of the SmPC).

Initiate/Continue treatment ☐ Yes ☐ No

▼ This medicinal product is subject to additional monitoring. Healthcare professionals are asked to report any suspected adverse events to: HPRA Pharmacovigilance via www.hpra.ie; Adverse events can also be reported to Orexigen®: +442039660116 or currax.mi@primevigilance.com