

Obesity and Covid-19



It is becoming increasingly clear that **obesity** is one of the biggest risk factors for severe COVID-19 disease, particularly among younger patients. This is important to consider given the prevalence of obesity in Ireland (23% adults)¹.

Newly published data from New York show that among those under 60, obesity was **twice as likely** to result in hospitalisation for COVID-19 and also significantly increased the likelihood that a person would end up in intensive care². Obesity in people < 60 years of age appears to be a previously unrecognised risk factor for hospital admission and need for critical care². The chronic condition with the strongest association with critical illness was **obesity**, with a substantially higher odds ratio than any cardiovascular or pulmonary disease³.

Meanwhile, a new French study shows a high frequency of obesity among patients admitted to one intensive care unit for COVID-19; furthermore, disease severity increased with increasing BMI⁴. A key finding was that those with a BMI > 35 kg/m² had a more than sevenfold increased risk of requiring mechanical ventilation, compared to those with a BMI < 25 kg/m², even after adjusting for age, diabetes, and hypertension⁴.

So, there is clear evidence linking obesity to COVID-19. And there are many other diseases and chronic conditions linked to obesity also. So now more than ever might be a good time to consider your patients who are living with obesity.

Obesity and COVID-19 HSE Clinical Guidance and Evidence is co-written by Prof Donal O'Shea, HSE Clinical Lead and Karen Gaynor, Programme Manager for the National Obesity Management Clinical Programme, and is available at: <https://hse.drsteevenslibrary.ie/c.php?g=679077&p=4845309>

Mysimba has been approved in the European Union since 2015 for use as an adjunct to a reduced calorie diet and increased physical activity for weight management in adults with an initial BMI of **30kg/m² or greater, or 27kg/m² or greater in the presence of at least one weight – related complication** (eg type 2 diabetes, dyslipidaemia, or controlled hypertension)⁵.

Mysimba is a fixed dose combination of the active substances Naltrexone and Bupropion, which together work on the two areas of the brain responsible for **hunger** (hypothalamus) and the body's **natural reward system** (mesolimbic system)⁵.

The exact neurochemical effects of Mysimba leading to weight loss are not fully understood. The individual components of Mysimba are not approved for weight loss.



Mysimba[®] (naltrexone/bupropion) Prescribing Information

Product name: Mysimba 8 mg/90 mg prolonged-release tablets. **Composition:** 8 mg naltrexone HCl, 90 mg bupropion HCl. **Indication:** 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 either (1) ≥ 30 kg/m² (obese), or (2) ≥ 27 kg/m² to < 30 kg/m² (overweight) and with one or more weight-related co-morbidities. Discontinue treatment after 16 weeks if patients have not lost at least 5% of their initial body weight. **Dosage and administration: Adults:** Escalate dose over 4 weeks, to a maximum recommended daily dose of two tablets twice daily. Evaluate the need for continued treatment after 16 weeks and re-evaluate annually. **Elderly patients (over 65 years):** Use with caution. Not recommended in patients over 75 years of age. **Paediatric population:** Should not be used in children and adolescents below 18 years. **Method of administration:** Swallow tablets whole with water and preferably with food; do not cut, chew or crush. **Contraindications:** Hypersensitivity to active substance(s) or to any of the excipients. Uncontrolled hypertension. Current seizure disorder or a history of seizures. Known central nervous system tumour. Acute alcohol or benzodiazepine withdrawal. History of bipolar disorder. Any concomitant treatment containing bupropion or naltrexone. Current or previous diagnosis of bulimia or anorexia nervosa. Dependency on chronic opioids or opiate agonists (e.g. methadone), or acute opiate withdrawal. Concomitant administration of monoamine oxidase inhibitors (MAOI); at least 14 days should elapse between discontinuation of MAOI and initiation of treatment with Mysimba. Severe hepatic impairment. End stage renal failure. **Warnings and precautions (see SmPC for full details): Suicide and suicidal behaviour:** Closely supervise patients particularly those at high risk, especially in early treatment and following dose changes. Seizures: Bupropion is associated with a dose-related risk of seizures. Exercise caution when prescribing to patients with predisposing factors that may increase the risk of seizure. **Patients receiving opioid analgesics:** Do not administer to patients receiving chronic opiates. The attempt to overcome any naltrexone opioid blockade by administering large amounts of exogenous opioids is very dangerous and may lead to a fatal overdose or life endangering opioid intoxication (e.g. respiratory arrest, circulatory collapse). **Allergic reactions:** Discontinue if experiencing allergic or anaphylactoid/anaphylactic reactions (e.g. skin rash, pruritus, hives, chest pain, oedema, and shortness of breath) during treatment. **Elevation of blood pressure:** Use with caution in controlled hypertension and do not use in uncontrolled hypertension. **Cardiovascular disease:** Use with caution in active coronary artery disease (e.g. ongoing angina or recent history of myocardial infarction) or history of cerebrovascular disease. **Hepatotoxicity:** Mysimba is contraindicated in severe hepatic impairment and not recommended in moderate hepatic impairment. In mild hepatic impairment reduce maximum dose to two tablets per day. Patients with suspected drug-induced liver injury should discontinue treatment. **Renal impairment:** Mysimba is contraindicated in end-stage renal failure; in moderate or severe renal impairment reduce maximum dose to two tablets per day. Dose reduction is not necessary in mild renal impairment. **Neuropsychiatric symptoms and activation of mania:** Use with caution in patients with a history of mania. **Lactose:** Do not use in patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption. **Other:**

The consumption of alcohol during Mysimba treatment should be minimised or avoided. **Effects on ability to drive and use machines:** The use of naltrexone/bupropion has been associated with somnolence and episodes of loss of consciousness. Patients who experience dizziness, somnolence, loss of consciousness or seizure should be advised to avoid driving or operating machines until these adverse effects have resolved. **Undesirable effects:** Adverse reactions reported in subjects who received Mysimba, naltrexone alone or bupropion alone. **Very common (≥1/10):** Anxiety; insomnia; headache; abdominal pain; nausea; constipation; vomiting; arthralgia; myalgia. **Common (≥1/100 to <1/10):** Lymphocyte count decreased; hypersensitivity reactions e.g. urticaria; decreased appetite; irritability; affective disorders; depression; dizziness; tremor; dysgeusia; disturbance in attention or concentration; lethargy; lacrimation increased; tinnitus; vertigo; hypertension; blood pressure increased; palpitations; heart rate increased; electrocardiogram change; hot flush; dry mouth; toothache; diarrhoea; abdominal pain upper; pruritus; alopecia; rash; ejaculation delayed; feeling jittery; fatigue. **FOR A FULL LIST OF ADVERSE EVENTS PLEASE CONSULT THE SUMMARY OF PRODUCT CHARACTERISTICS. NET Wholesale Price:** €83.00 per box of 112 tablets. **Legal Classification:** POM. **MA number:** EU/1/14/988/001. **Marketing Authorisation Holder:** Orexigen Therapeutics Ireland Limited, 2nd Floor, Palmerston House, Fenian Street, Dublin 2, Ireland. **Further information is available on request from:** Consilient Health Ltd, Block 2A Richview Office Park, Clonskeagh, Dublin 14 or Mysimba@druginfo.com. **Date of preparation of P I:** December 2019.

This medicinal product is subject to additional monitoring. Healthcare professionals are asked to report any suspected adverse events to: www.hpra.ie. Click on "I want to report an issue" and then click on "Human medicines adverse events report" to record any suspected adverse events. Adverse events should also be reported to Orexigen[®]: 1-800-902-210 or Mysimba@druginfo.com.

References

1. Obesity and COVID-19 HSE Clinical Guidance and Evidence <https://hse.drsteevenslibrary.ie/c.php?g=679077&p=4845309>
2. Obesity in patients younger than 60 years is a risk factor for Covid-19 hospital admission. Jennifer Lighter, MD et al. Clinical Infectious Diseases. Published: 09 April 2020. <https://doi.org/10.1093/cid/ciaa415>.
3. Factors associated with hospitalization and critical illness among 4,103 patients with COVID-19 disease in New York City Christopher M. Petrilli et al. medRxiv. Published: 11 April 2020. doi: <https://doi.org/10.1101/2020.04.08.20057794>.
4. High prevalence of obesity in severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) requiring invasive mechanical ventilation. Arthur Simonnet et al. Obesity. Published: 09 April 2020 <https://doi.org/10.1002/oby.22831>.
5. Mysimba Summary of Product Characteristics available at www.medicines.ie.



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