

PRACTICE NOTICE 4

Control of the supply of non prescription medicinal products containing orlistat 60mg (alli®)

The European Medicines Agency (EMA) has reclassified the centrally authorised medicine containing orlistat 60mg (alli®) from prescription-only to non-prescription in the EU.

Alli® (60mg) is used, in conjunction with dieting and exercise, with a view to weight loss in the case of overweight patients who have a body mass index (BMI) of 28 or above.

This medicine is now available in Ireland through retail pharmacy businesses without a prescription.

Article 10 of the Regulation of Retail Pharmacy Businesses Regulations 2008 require that when supplying any non prescription medicinal product a pharmacist must be satisfied that:

- (a) the purchaser is aware of the appropriate use of the medicine
- (b) the medicine is being sought for that use, and
- (c) as far as the pharmacist is aware, the product is not intended for misuse and/or abuse.

In the supply of alli® to a patient, it is important that the pharmacist must also ensure compliance with the conditions of the Marketing Authorisation which includes the following:

Treatment programme: Diet and exercise are important parts of a weight loss programme. It is recommended that a diet and exercise programme is started before beginning treatment with orlistat and pharmacists should ensure this programme is started before considering the supply of orlistat.

Indication; weight loss in adults who are overweight (body mass index (BMI) ≥ 28 kg/m²) and should be taken in conjunction with a mildly hypocaloric, lower-fat diet.

Age: should not be used in children and adolescents below 18 years of age.

Dosage: one 60 mg capsule to be taken three times daily. This dosage should not be exceeded.

Treatment duration: If patients have been unable to lose weight after 12 weeks of treatment with orlistat, they should consult their doctor or a pharmacist. It may be necessary to discontinue treatment. Treatment should not exceed 6 months.

Special warnings and precautions: Special care should be taken with patients already on medication for high blood pressure, high cholesterol or diabetes. In addition, orlistat may reduce the effectiveness of oral contraceptives particularly in cases of severe diarrhoea. Because of the potential reduction in the absorption of fat-soluble vitamins, patients should be advised to use a multivitamin supplement.

For full information on this product, including information on special warnings, precautions, contraindications, drug interactions and side-effects, you are referred to the Summary of Product Characteristics (SPC). This SPC is available from the European Medicines Agency website-
<http://www.emea.europa.eu/humandocs/PDFs/EPAR/alli/H-854-PI-en.pdf>

Each superintendent and supervising pharmacist must ensure that any retail pharmacy business for which he or she is responsible has appropriate policies and procedures in place to ensure compliance with all of the above. In addition, these policies and procedures must be in conformity with the provisions of the statutory PSI Code of Conduct for Pharmacists which encourages the rational and proper use of medicines in the interest of the patient. In general, this Code requires that pharmacists provide honest, relevant, accurate, current and appropriate information to patients regarding the nature, cost, value and benefit of any medicine, health related product or service that he or she may provide.