

# PRACTICE GUIDANCE: OTC ORLISTAT

Following reclassification from prescription-only to pharmacy medicine status, orlistat 60mg is now available for sale over the counter (OTC). This guidance outlines the OTC indications for the drug, as well as important points to consider when counter prescribing



Royal  
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## BACKGROUND

Tackling obesity has been identified as a national Government priority.

In **England**, according to 2006 figures<sup>1</sup>, 23.7% of men and 24.2% of women are obese and almost two-thirds (61.6%) of all adults are either overweight or obese.

The prevalence of obesity in adults in **Scotland** (2007 data<sup>2</sup>) is similar reaching 22% in men and 24% in women in 2003 with marked increases in men aged 35-64 years and in women aged 35-44 years.

The figures are slightly lower in **Wales** (2003 data<sup>3</sup>) with 57% of adults classified as overweight or obese, including 21% obese.

A Foresight report<sup>4</sup> on tackling obesities highlighted that by 2050, 60% of men and 50% of women could be clinically obese. Without action, obesity-related diseases will cost an extra £45.5 billion per year.

'Healthy Weight, Healthy Lives: a cross-Government strategy for England'<sup>5</sup> and 'Pharmacy in England: building on strengths – delivering the future'<sup>6</sup> discuss ways of reversing the rising tide of obesity and overweight in population.

In Scotland, 'Healthy Eating Active Living: action plan to improve diet, increase physical activity and tackle obesity'<sup>7</sup> outlines how the Scottish Government aims to improve the nation's diet, encourage greater physical activity and begin to establish a base for tackling obesity through both targeted interventions and by supporting people in achieving and maintaining a healthy weight.

'Health Challenge Wales'<sup>8</sup> signposts members of the public to information or activity to help them improve their own health. It also engages with organisations to look after the health of their staff and customers.

## CODE OF ETHICS

Pharmacists are reminded of the principles of the 'Code of Ethics for Pharmacists and Pharmacy Technicians' and 'Professional Standards

and Guidance Documents' that support and supplement aspects of the Code ([www.rpsgb.org/protectingthepublic/ethics/](http://www.rpsgb.org/protectingthepublic/ethics/)).

In terms of orlistat supply, particular attention is drawn to professionals standards and guidance for supply of OTC medicines ([www.rpsgb.org/pdfs/coepsgssmeds.pdf](http://www.rpsgb.org/pdfs/coepsgssmeds.pdf)) and internet pharmacy services ([www.rpsgb.org/pdfs/coepsgintpharm.pdf](http://www.rpsgb.org/pdfs/coepsgintpharm.pdf))

## COMMUNICATION – PRIVACY AND CONFIDENTIALITY

Requests for orlistat supply / weight management advice should be handled sensitively and the customer's right to privacy and confidentiality respected.

Pharmacy users are entitled to a confidential consultation with their pharmacist although not all pharmacy users will be aware of this. Pharmacists may therefore consider advertising that all advisory services and consultations are confidential and that, where appropriate, a private area is available.

Pharmacists are encouraged to display a notice in the pharmacy encouraging pharmacy users to inform a member of staff if they require a more private consultation for any purpose.

## BODY MASS INDEX

Body Mass Index (BMI) is a simple index of weight-for-height that is commonly used to classify underweight, overweight and obesity in adults. It is defined as the weight in kilograms divided by the square of the height in metres (kg/m<sup>2</sup>).

BMI has its limitations and may not always provide an accurate reflection of whether a person needs to lose weight e.g. in individuals who are highly muscular (muscle weighs more than fat), women who are pregnant or breastfeeding. Some groups, such as Asian populations and older people have co-morbidity risk factors that are a concern at different BMIs – lower BMIs for Asian populations and higher BMIs for older people.

## POINTS TO CONSIDER WHEN RECOMMENDING ORLISTAT

- Orlistat should be supplied in accordance with the terms of the marketing authorisation. Supply to under 18s and those with a BMI <28 kg/m<sup>2</sup> (including those customers whose BMI drops to less than 28 kg/m<sup>2</sup> following an initial purchase) fall outside the terms of the marketing authorisation. Satisfy yourself that the client is 18 or over and has a BMI ≥ 28 kg/m<sup>2</sup> early in the consultation. Refuse to make a supply where there are reasonable grounds for suspecting misuse.
- Remind customers that orlistat should be taken in accordance with the manufacturers' dosage instructions and dietary recommendations. A balanced healthy diet and regular physical activity should ideally be started before beginning treatment with orlistat and continue to be followed when treatment is stopped.
- Users need to moderate their fat intake. For example on a diet of 1400 calories per day this would equate to 15g fat per meal (based on three meals a day). The actual calorie intake and fat consumption to be followed is dependent on the user's initial weight and level of physical activity - further guidance is provided in the package leaflet. Consumption of a lower-fat diet will decrease the likelihood of experiencing diet-related side effects - wind (flatulence), with or without oily spotting / sudden bowel motions / soft stools / fatty oily stools (steatorrhea).
- Equipment (weighing scales / height measures) used in the pharmacy must be maintained in good order and must be fit for the intended purpose. Ensure that they are used in accordance with the manufacturers' instructions e.g. calibrated.
- Realistic targets for weight loss (adults) are usually a maximum weekly weight loss of 0.5 to 1kg (1-2 lb) a week and an overall weight loss of 5-10% of original weight<sup>9</sup>. Monitoring and recording weight on a regular basis within the pharmacy setting or by the customer may encourage people to keep motivated. Consider keeping a record, if possible, of the sale of orlistat / BMI measurement in the patient medication record. The individual's permission should be sought before a record is made.
- Always check the BMI of individuals requesting orlistat on each occasion they make a request and be alert for signs of an eating disorder or possibility of substance misuse e.g. purchasing large quantities and /or a wide range of laxatives or diuretics.
- Overweight or obese people may be at increased risk of health problems (cardiovascular disease, some cancers, high cholesterol, type 2 diabetes, raised blood pressure). Offer or signpost to a vascular check service (or free NHS Health Check – England only) if appropriate.
- Reclassifying orlistat provides an opportunity for pharmacists to promote healthy lifestyle interventions: regular exercise, eating a healthy diet and diabetic control, stop smoking programmes. Diagnostic / screening services (cholesterol, diabetes, blood pressure monitoring etc) may be offered to some customers if appropriate.
- See also Society practice guidance on obesity, stop smoking, cholesterol testing, blood pressure monitoring, diagnostic testing and screening services ([www.rpsgb.org](http://www.rpsgb.org)) and PharmacyHealthLink resources to support pharmacists give health information to the public ([www.pharmacyhealthlink.org.uk](http://www.pharmacyhealthlink.org.uk)). The Centre for Pharmacy Postgraduate Education ([www.cppe.ac.uk](http://www.cppe.ac.uk)) has also produced an open learning programme on weight management.

## The International Classification of adult underweight, overweight and obesity according to BMI

BMI less than 18.5 – underweight  
BMI between 18.5 and 24.9 – normal weight  
BMI between 25.0 and 29.9 – overweight  
BMI 30.0 or above – obese

Source: World Health Organization website.  
[http://www.who.int/bmi/index.jsp?introPage=intro\\_3.html](http://www.who.int/bmi/index.jsp?introPage=intro_3.html)

## OTC INDICATIONS

OTC orlistat is indicated for weight loss in adults (18 or over) who are overweight (body mass index  $\geq 28$  kg/m<sup>2</sup>) and should be taken in conjunction with a mildly hypocaloric, lower-fat diet (for further details see How To Take OTC Orlistat).

*Measuring waist circumference is not a requirement for supply of OTC orlistat.*

## HOW ORLISTAT WORKS

Orlistat is a potent, specific and long-lasting inhibitor of gastrointestinal lipases. It acts locally within the digestive system to prevent dietary fat absorption, so there is a minimal absorption of the active ingredient in the bloodstream. It exerts its therapeutic activity by forming a covalent bond with the active serine site of the gastric and pancreatic lipases. The inactivated enzyme is thus unavailable to hydrolyse dietary fat (triglycerides) into absorbable free fatty acids and monoglycerides. It is estimated that orlistat 60mg taken three times daily blocks the absorption of approximately 25% of dietary fat.

## HOW TO TAKE OTC ORLISTAT

The recommended dose of orlistat is one 60mg capsule three times daily. The capsule should be taken with water immediately before, during or up to one hour after each main meal. If a meal is missed or contains no fat, the dose of orlistat should be omitted.

No more than three 60mg capsules should be taken in 24 hours.

Diet and exercise are important parts of a weight loss programme and ideally should be started before beginning treatment with orlistat. While taking orlistat, the customer should be on a nutritionally balanced, mildly hypocaloric diet that contains approximately 30% of calories from fat (e.g. in a 2000kcal/day diet, this equates to <67g of fat). The daily intake of fat, carbohydrate and protein should be distributed over three meals. The diet and exercise programme should continue to be followed when treatment with orlistat is stopped.

If the customer has been unable to lose weight after 12 weeks of treatment at the recommended dosage and in conjunction with the requisite lifestyle changes, he/she should be advised to stop taking OTC orlistat and to seek medical advice. If they are having no benefit from OTC orlistat they should not continue to take it.

**Treatment should not exceed 6 months.**

## CONTRA-INDICATIONS

- Hypersensitivity to the active substance or to any of the excipients
- People taking ciclosporin
- People taking warfarin or other oral anticoagulants
- People with chronic malabsorption syndrome
- People with cholestasis (condition where the flow of bile from the liver is blocked)
- Pregnant or breast-feeding women

## SPECIAL WARNINGS / PRECAUTIONS

- As weight loss may be accompanied by improved metabolic control in diabetes, those taking a product for diabetes should consult a healthcare professional **before** taking orlistat, in case it is necessary to adjust the dose of the antidiabetic product.
- Weight loss may be accompanied by an improvement in blood pressure or cholesterol levels. Pharmacists should raise awareness that it may be necessary to adjust the dose of medicinal products for hypertension or hypercholesterolaemia when taking orlistat.
- Pharmacists should inform those taking amiodarone to liaise with their prescriber **before** starting treatment with orlistat. The dose of amiodarone may need to be adjusted during treatment with orlistat (see Drug Interactions)
- Cases of rectal bleeding have been reported in individuals taking orlistat. If this occurs, advise the individual to consult a doctor.
- The use of an additional contraceptive method is recommended to prevent possible failure of oral contraception that could occur in case of severe diarrhoea (see Drug Interactions).
- Treatment with orlistat may potentially impair the absorption of fat-soluble vitamins (A, D, E and K). For this reason, a multivitamin supplement should be taken by all users of orlistat at bedtime (see Drug Interactions)
- Steatorrhoea has a different aetiology to diarrhoea – if steatorrhoea occurs advise users against the use of antimotility agents.

## ADVERSE EFFECTS

Adverse reactions are largely gastrointestinal in nature and related to the pharmacologic effect of orlistat on preventing the absorption of ingested fat. 'Diet-related

treatment effects' include: wind (flatulence), with or without oily spotting / sudden bowel motions / soft stools / fatty oily stools (steatorrhoea).

Diet-related effects typically occur about 1-2 days after taking orlistat with a high fat meal and are dependent on gastrointestinal transit time (varies between individuals and is affected by food / drink previously consumed).

Other common effects include anxiety, abdominal pain, liquid stools, faecal incontinence and increased defaecation. Diverticulitis, hypersensitivity reactions, skin blistering, hepatitis, cholelithiasis and mild rectal bleeding have also been reported. See SPC for full details.

Pharmacists are reminded to send a yellow card report to the Medicines and Healthcare products Regulatory Agency if a serious adverse drug reaction is suspected.

## DRUG INTERACTIONS

**Ciclosporin** – decrease in ciclosporin plasma levels. Orlistat use is contraindicated.

**Oral anticoagulants (including warfarin)** – international normalised ratio (INR) could be affected. Orlistat is contraindicated.

**Oral contraceptives** – there is no drug-drug interaction seen between orlistat and oral contraceptives in clinical studies. However, orlistat may indirectly reduce the availability of oral contraceptives and lead to unexpected pregnancies in some individual cases. Advise users to use an additional contraception method if they experience severe diarrhoea.

**Acarbose** – in the absence of pharmacokinetic interaction studies, orlistat is not recommended for use in those taking acarbose.

**Amiodarone** – a decrease in plasma levels of amiodarone

## CHECKLIST

This checklist is intended to help pharmacists elicit the necessary information to determine whether OTC supply of orlistat is appropriate.

**Where should the consultation take place?** – consultation room / private consultation area

**What questions do I need to ask?** – is the client presenting in person, age, other medication (including OTC or herbal remedies), previous medical history, current diet/exercise

**What actions do I need to take?** – BMI check (weight and height) / consider privacy and confidentiality issues / equipment fit for purpose

**What considerations (from answers) do I need to make?** – any interactions or contra-indications / any doubts regarding age / BMI <28kg/m<sup>2</sup> / possible misuse / previous duration of treatment

**Can I proceed with the sale?** Yes/No and why (consider record-keeping)

**If yes, what other information do I need to give the purchaser?** – how to use, action of drug and side effects, managing diet-related treatment effects, special warnings and precautions, appropriate diet and exercise advice, promotion of steady consistent weight loss within realistic parameters, promotion of healthy lifestyle interventions.