Patient Group Direction for the Supply of Orlistat (Xenical) from Designated Community Pharmacies

Written by: Sheila Brown, Prescribing Adviser
Date: September 2006
Reviewed by: 

Ratified by: East Kent PGD Professional Advisory Group

Signed by:
Pharmacist – Sarah Leaver, Community Health Specialist Pharmacist
Doctor – Dr J Rodriguez, Director of Public Health
Clinical Governance – Fiona Stephens, Clinical Governance Nurse
Date: November 2006

Review Date: November 2008

If you have any comments to make about this Patient Group Direction please contact Sarah Leaver, Community Health Specialist Pharmacist, Chair of East Kent PGD Steering and Professional Advisory Groups – Tel: 01303 717010 Email: sarah.leaver@ekentmht.nhs.uk
Clinical Condition

**Indication**

Orlistat is indicated in conjunction with a mildly hypocaloric diet for the treatment of the following groups of clients:

- Clients who are obese (i.e. with a BMI $\geq 30\text{kg/m}^2$) but who are actively participating in a weight management programme and who have demonstrated motivation to change dietary behaviour.
- Clients who are overweight (i.e. BMI $\geq 28\text{kg/m}^2$) with one or more co-morbidity, such as hypertension, dyslipidaemia or type 2 diabetes who also are actively participating in a weight management programme and who have demonstrated motivation to change dietary behaviour.

Treatment with orlistat should be discontinued after 12 weeks if patients have been unable to lose at least 5% of the body weight as measured at the start of drug therapy. Treatment should be reviewed at 12 months.

**Inclusion criteria**

Clients must be registered with a GP based within the Eastern & Coastal Kent Organisation and be willing to accept treatment from a pharmacist.

- BMI $\geq 30\text{kg/m}^2$
- BMI $\geq 28\text{kg/m}^2$ with at least one co-morbidity
- Lifestyle changes must be followed for at least 8 weeks before anti-obesity drugs are used
- Age 18-75 years
- Informed verbal consent to treatment and adherence to appropriate dietary intake
- Referral from local GP/dietician

**Exclusion criteria**

- BMI $< 28\text{kg/m}^2$
- Age under 18 years or over 74 years
- Refusal of consent
- Known hypersensitivity to orlistat or its excipients
- Current cholestasis
- Breast feeding or pregnancy
- Concurrent administration of cyclosporin, acarbose, sibutramine or other weight loss agents
- Chronic malabsorption syndrome
- Concurrent administration of insulin*
- Post bariatric surgery

*Within the terms of its SPC, orlistat may be used in patients who are on insulin. However, there may be an increased risk of hypoglycaemia in these patients as weight loss can lead to improvement in glycaemic control. These patients therefore warrant special care so that the dose of insulin may be appropriately monitored.
### Exclusion criteria

Patients not eligible for treatment under this protocol will be recommended to refer to their GP for further assessment and advice.

Criteria for referral:
Clients should be referred to their GP:
- When client is considered eligible for orlistat therapy under a weight loss programme, but supply through pharmacy is not recommended through the exclusion criteria

This might include any of the conditions referred to as exclusion criteria above, but also:
- Previously unrecognised co-morbidities:
- BP > 140/85 or BP > 130/80 (known diabetes) on three consecutive occasions
- Uncontrolled symptoms
- Uncontrolled symptoms of other illnesses that are a cause for concern e.g. mental health, orthopaedic problems
- Inadequate weight loss
- < 5% weight loss within three months of initiation of treatment

### Cautions/Need for further advice

**Drug Interactions:** The concomitant administration of orlistat is not recommended with the following:
- Acarbose
- Anorectic drugs
- Amiodarone

Administration in patients taking warfarin or other anticoagulants, international normalised ratio (INR) values should be monitored, therefore these patients should be referred for INR monitoring

N.B. Vitamins and beta-carotene: Decreases in the absorption of vitamins D, E and beta-carotene should be taken into account. Malabsorption is a theoretical concern, but not an issue in most people treated in Primary Care.

If fat soluble vitamins are necessary, they should be given at least 2 hours after a dose of orlistat or at bedtime.

### Action if patient declines or is excluded

Patients not eligible for treatment or declining treatment under this protocol will be recommended to refer to their GP for further assessment and advice.
**Drug Details**

| **Name, form & strength of medicine** | Orlistat is supplied as 120mg hard capsules in blister packs containing 84 capsules.  
Legal classification POM  
The capsule is presented as turquoise body bearing the imprint of “ROCHE Xenical 120” |
| **Route/Method** | Oral |
| **Dosage & Frequency** | The recommended dose of orlistat is one 120mg capsule which should be taken immediately before, during or up to one hour after each main meal (2-3 times daily). If a meal is missed or contains no fat, the dose of orlistat should be omitted. |
| **Duration of treatment** | This will be determined by the pharmacist, but will normally follow the following guidelines:  
- Treatment with orlistat should be discontinued after 12 weeks if patients have been unable to lose at least 5% of the body weight as measured at the start of drug therapy  
Client should undergo a review with GP at 12 months |
| **Maximum or minimum treatment period** | There is no restriction on duration of treatment according to product licence. |
| **Quantity to supply/administer** | A maximum of 5 supplies will be made by the pharmacist under the PGD. Each supply will be for 84 x 120mg orlistat capsules. |
| **Side effects** | Adverse reactions to orlistat are largely gastrointestinal in nature:  
- Oily spotting from rectum  
- Flatus with discharge  
- Faecal urgency  
- Fatty/oily stool  
- Oily evacuation  
- Increased defaecation  
- Faecal incontinence  
Other treatment-emergent adverse events that occurred at a frequency of >2% and with an incidence >1% above placebo are detailed in Appendix 1. |
Additional facilities and supplies

The pharmacy premises will be equipped with weighing scales and height measure to allow calculation of patients BMI (Body Mass Index) and blood pressure meters.

Orlistat should be stored in a cool place.

Orlistat when issued is to be labelled with the date of dispensing and the client's name, according to pharmacy procedures on the patient medication record system. A mechanism should be put in place to ensure that the patient record acknowledges the supply of orlistat under PGD. Prescription charges need to be collected in the usual manner, and exempt patients will need to fill in a declaration form.

Informed consent;
The pharmacist will need to obtain the name, address, and date of birth of the client and record these details for submission monthly to Eastern & Coastal Kent PCT to arrange payment. Client information relating to the supply of orlistat under PGD has to be passed to other health service organisations, such as a client's GP or the local NHS commissioning body, for a variety of purposes such as audit or payment.
The client’s informed consent must be obtained before information can be passed to their GP.

Advice to patient/carer

The advice to clients should include specific product advice, in addition to general advice relating to physical activity and diet:

- Orlistat must be taken with recommended healthy balanced diet containing less than 30% energy (calories) from fat.
- 1 x 120mg capsule orlistat should be taken immediately before, during or up to 1 hour after each main meal (2-3 times daily)
- If a meal is missed or contains no fat, the dose of orlistat should be omitted
- The capsules should be stored in a cool place

It is recommended that the client read the appropriate enclosed information leaflet, which should be given to the client at the time of supply. This gives details of how to take orlistat and how to modify dietary intake appropriately.

Advise client to register with MAP (Motivation: Advice: Proactive support), the Roche sponsored freephone supportline, and provide them with some information about the service: 0800 731 7138.

Adverse outcomes;
Clients must be advised to follow a healthy balanced dietary intake with no more than 30% of calories from fat, while taking orlistat.
Advice to patient/carer
Cont’d………..

If the caloric intake exceeds 30% of energy from fat, then patients may experience gastrointestinal side effects such as:
• Oily spotting from rectum
• Flatus with discharge
• Faecal urgency
• Fatty/oily stool
• Oily evacuation
• Increased defaecation
• Faecal incontinence

Clients should be advised about this at the time of dispensing orlistat and advised that, providing a balanced diet with appropriate fat intake is followed, these treatment effects can be managed and are less likely to occur. Any event of this nature suggests that the dietary intake has been inappropriate and may reflect hidden fat in the diet, alerting the client to this possibility.

Clients should be able to modify their dietary intake appropriately to avoid these treatment effects.

[For the pharmacist they are an indication that the client is not following the recommended low fat diet and appropriate dietary advice and follow up should be made available]

Follow up

Clients will be assessed at least monthly throughout the treatment period, under the weight management programme. BMI, waist circumference and blood pressure will be assessed at monthly intervals.
## Staff Characteristics

### Qualifications
A member of the Royal Pharmaceutical Society of GB and a practicing community pharmacist, working in a pharmacy accredited by Eastern and Coastal Kent PCT.

### Specialist competencies or qualifications
- Has undertaken appropriate training and successfully completed the competencies to undertake the clinical assessment of patient leading to diagnosis that requires treatment according to the indications listed in this PGD – having attended the training session on weight management.
- Has undertaken appropriate training for working under PGDs for the supply and administration of medicines.
- Have completed the self-directed learning package on orlistat.

### Continuing training & education
The practitioner should be aware of any change to the recommendations for the medicine listed. It is the responsibility of the individual to keep up-to-date with continued professional development and to work within the limitations of individual scope of practice.

## Referral Arrangements and Audit Trail

### Referral arrangements
As per local arrangements/national guidelines.

### Records/audit trail
- Patient’s name, address, date of birth and consent given.
- Contact details of GP (if registered).
- Diagnosis or working diagnosis.
- Dose and form supplied (and batch details).
- Advice given to patient (including side effects).
- Pharmacist signature, printed name, date and time relating to supply of the medication, and also, if relevant, pharmacist signature, name, date and time when medication was removed or discontinued.
- Details of any adverse drug reaction and actions taken including documentation in the patient’s medical record.
- Referral arrangements.

## References/Resources and comments
This patient group direction must be agreed to and signed by all health care professionals involved in its use. The NHS Trust should hold the original signed copy. The PGD must be easily accessible in the clinical setting.

Organisation

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Authorisation

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<td>Clinical Governance Lead</td>
<td>Fiona Stephens</td>
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<td>22.11.06</td>
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<tr>
<td>Lead Pharmacist</td>
<td>Sarah Leaver</td>
<td>Community Health Specialist Pharmacist</td>
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<td>Lead Doctor</td>
<td>Dr J Rodriguez</td>
<td>Director of Public Health</td>
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Patient Group Direction Peer Reviewed by

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Individual Authorisation

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY. It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct.

Note to Authorising Managers and GPs: authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation. This Patient Group Direction is to be read, agreed to and signed by all registered nurses it applies to. One copy should be given to each nurse with the original signed copy being kept by the nominated GP with responsibility for PGDs within the practice.

I confirm that I have read and understood the content of this patient group direction and that I am willing and competent to work under it within my professional code of conduct.

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