Orlistat (ALLI®) now available OTC

Approved indication
ALLI® is indicated, in conjunction with a reduced calorie intake, for the treatment of obese patients with a body mass index ≥ 30 kg/m² and for the treatment of overweight patients with a body mass index ≥ 27 kg/m² who also have other obesity-related co-morbidities such as hypertension, dyslipidaemia or type 2 diabetes.

Mode of action
Orlistat is an inhibitor of gastric and pancreatic lipases, selectively reducing the breakdown and the absorption of dietary fat.1 By preventing the absorption of fat, orlistat helps reduce the calorie intake from dietary fat which, in turn, has a positive effect on reducing overall calorie intake and inducing weight loss.

Dosage
Orlistat has been available on prescription-only as a 120 mg capsule. Since orlistat has a well-established safety profile, it has been registered by the Food and Drug Administration (FDA) in the USA and by the Medicines Control Council in South Africa for over-the-counter use as a 60 mg dose. Adults over 18 years of age: One capsule (60 mg) to be taken up to three times a day.

The capsule should be taken with water immediately before, during or up to 1 hour after each main meal. No more than three capsules are to be taken in any 24-hour period. Treatment should continue until target weight loss is achieved. However, most weight loss occurs in the first six months of therapy.1

While taking orlistat, patients should be eating a nutritionally balanced, mildly hypocaloric diet that contains approximately 30% of calories from fat.1

Evidence of efficacy
The efficacy of orlistat 120 mg has been demonstrated in several clinical trials. A 3-month, open-label, naturalistic study with orlistat 60 mg was conducted in an over-the-counter (OTC) setting in 18 pharmacies.2 Results indicated that orlistat 60 mg is an appropriate weight loss therapy in the OTC environment. Approximately, 80% of patients in the study indicated that they were satisfied or very satisfied with the weight loss achieved. Measured and self-reported relative median weight loss was approximately 5% after 60 days of using orlistat.2

Precautions
• General
Orlistat is contraindicated in patients with chronic malabsorption syndrome, cholestasis or known hypersensitivity to orlistat or to any of the components of the formulation.1

• Pregnancy and lactation
Orlistat should not be used during pregnancy or lactation.

Major adverse effects
Most common adverse events are gastrointestinal and include oily stools, faecal urgency and oily spotting. These side effects tend to occur when treatment is started but subside with time as patients become accustomed to eating a low-fat diet of no more than 30% fat.1

Drug interactions
Orlistat is contraindicated in patients taking ciclosporin. Patients taking warfarin should be cautioned that the International Normalised Ratio (INR) value may be affected by orlistat. An interaction with amiodarone has been reported and patients receiving amiodarone should only take orlistat under the supervision of a doctor.

Orlistat may decrease the absorption of fat-soluble vitamins and patients taking orlistat should be advised to take a multivitamin supplement once-daily at bedtime that contains the oil-soluble vitamins A, D, E and K and beta-carotene.

Cost: SEP (Incl VAT)
ALLI® 60 mg capsules 42: R159.60
ALLI® 60 mg capsules 84: R319.20
GlaxoSmithKline

Patient information
Counsel all patients receiving treatment with orlistat 60 mg (ALLI®) that:
• Weight loss should exceed 2 kg during the first month of therapy and should be 5% less than starting weight after three months of therapy.
• Treatment should be discontinued after 12 weeks if the patient has been unable to lose at least 5% of initial body weight as measured at the start of therapy.
• Medicines do not cure obesity and once the maximal therapeutic effect has been achieved, weight loss ceases. Therefore, it is important for patients to maintain diet and lifestyle modifications for sustained weight loss.

Conclusion
Diet and exercise remain the cornerstones for any weight loss programme. However, pharmacotherapy may be a helpful component for overweight and obese patients. The combination of medication and lifestyle modification has been shown to be more effective than either approach alone.

Orlistat 60 mg provides the pharmacist with an effective pharmacological option for weight loss, suitable for long-term use and without significant safety concerns that may be recommended for obese and overweight patients presenting in the pharmacy. The pharmacist is in the ideal position to counsel and support patients in their endeavours to lose weight and adopt a healthier lifestyle.

References:
1. ALLI® Package Insert.