

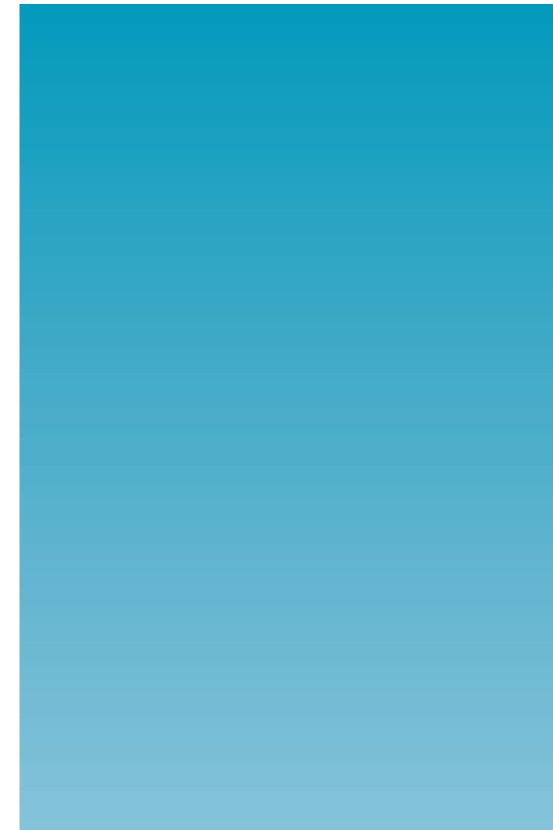
Conclusions by the researchers

- The use of orlistat 60 mg in conjunction with self-instructional lifestyle materials and in the absence of physician intervention resulted in high satisfaction, excellent dosing compliance, and utilisation of the educational materials
- The findings provide assurance that orlistat 60 mg is an appropriate weight loss drug for OTC use.

Key messages

- Orlistat 60 mg can be used appropriately and safely and with high consumer satisfaction without physician supervision or dietary counselling
- Half of the subjects (51%) reported positive behavioural changes in diet and physical activity during the study
- About 90% of subjects achieved weight loss at the end of the study
- The safety profile was consistent with results from randomised, placebo-controlled trials with orlistat
- Although just over half of the subjects did not experience GI AEs (diet-related treatment effects), of those who did, most continued to take orlistat
- Only 8.5% of subjects stopped treatment due to diet-related treatment effects
- Orlistat 60 mg is an appropriate weight loss therapy in the OTC environment.

Compliance, Behaviour Change, and Weight Loss with Orlistat in an Over-the-Counter Setting



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Aims of the study

The study was conducted to provide information on how consumers would use orlistat 60 mg, especially in terms of product dosing, in a setting without physician supervision.

Treatments being studied

Orlistat 60 mg

Subjects were allowed to take 1-2 capsules up to 3 times a day

Treatment period

3 months

Design of the study

A 3-month, open-label, 'real world' study was conducted in an over-the-counter (OTC) setting in 18 pharmacies in the US. Consumers (≥ 18 years) were allowed to purchase orlistat packages containing a bottle of orlistat 60 mg capsules plus educational materials, which provided lifestyle information and tools to encourage successful weight loss. Data were collected at pharmacy visits and during telephone interviews at 14, 30, 60, and 90 days after enrollment.

- Advertisements for the study targeted mild to moderately overweight adults
- The only restriction at screening was age (≥ 18 years)
- The consumers read the pack carton label before deciding whether to buy the product
- In the study orlistat 60 mg was labeled as appropriate for individuals who were mild to moderately overweight and needed to lose up to 30 lbs (13.6 kg). This corresponds to an approximate BMI between 25-29.9 kg/m²
- Exclusion criteria were reviewed with those who wanted to buy the product and who gave informed consent for the study
- The pack carton label described what to do when using the product and dosage instructions. The importance of eating meals that are low in fat and calories was emphasized
- In addition to a bottle of capsules (90 count), the package also included lifestyle advice and tools to encourage successful weight loss
- During the enrollment visit, demographic (including height and weight), medical and diet history data were collected
- The follow-up telephone interviews reviewed product use, adverse events, use of educational materials, contact with a doctor or pharmacist, multivitamin use and satisfaction with the product
- Self-reported weight loss was solicited at each interview. Only those who indicated they had lost weight were asked how much weight had been lost.

Primary endpoint

Not applicable

Secondary endpoint

Not applicable

Number of patients in the study

703 subjects screened (and told that they needed to buy the product at the intended market price)

339 subjects interested in purchasing the medication

290 subjects met inclusion/exclusion criteria

284 subjects purchased product (of whom 22 were protocol violators and excluded from all analyses other than safety analysis)

User population = 262

Safety population = 284

237 subjects used medication and completed at least one interview

Inclusion/exclusion criteria & demographics

Exclusion criteria included:

- Participation in previous orlistat market research studies
- Previously prescribed orlistat
- Currently treated with medication for diabetes
- Warfarin or cyclosporine
- Pregnant
- Breast-feeding.

Of 237 subjects who used orlistat and completed at least one interview, 85% were female, 82% white, average age 44.9 years, average BMI 32 kg/m², average weight 195 lbs (88 kg).

Main results

***Please note that subjects were allowed to take 1-2 capsules up to 3 times a day. This exceeds the currently recommended dose for alli**

- The product did not appeal to people who were not overweight. Only 8% had a BMI < 25 kg/m², most of whom (83%) were in the range of 22-24.9 kg/m², but none had a BMI < 18.5 kg/m². Most of the subjects (~ 60%) were obese (BMI > 30)
- Most subjects took 2-3 capsules per day
- At enrollment, 26% of subjects reported following a diet plan. On day 14 and day 90, ~ 80% and ~ 61% reported following a diet. Diets most commonly reported were reduced fat and reduced calorie
- Two weeks after starting to use orlistat, 78% of people who were on a diet were following a reduced fat diet
- Over 90% who reported following a diet indicated that they were successful in maintaining their diet. These results remained consistent at every interview for the duration of the study
- At the time of enrollment, 75% of subjects reported following an exercise programme (self-imposed or supervised). Over the study duration, 51% of subjects reported more frequent or longer exercise relative to enrollment
- Approximately, 79% of subjects who had a final interview (N=198) reported using at least one of the educational materials provided. Each of the tools was rated as useful or very useful by 80% of subjects who used them
- About 90% of subjects achieved weight loss at the end of the study (83% based on measured weight loss and 93% based on self-reported data)*
- Almost 50% of subjects achieved $> 5\%$ weight loss at the end of the 3 month study (measured weight loss, 46% of subjects; self-reported weight loss, 47% of subjects)*
- About 80% of the subjects were satisfied or very satisfied with orlistat* and this percentage remained consistent across all four interviews. The main reasons provided for satisfaction were weight loss (63% of subjects) and the drug was working (55% of subjects)
- The most commonly observed adverse events (AEs) were gastrointestinal (GI) in nature. Just over half of the subjects (52% of 284 orlistat users) did not develop orlistat-specific GI AEs (diet-related treatment effects) and overall, only 8.5% discontinued due to these events. (Of those who did develop GI AEs, 18% withdrew).