The study listed may include approved and non-approved uses, formulations or treatment regimens. The results reported in any single study may not reflect the overall results obtained on studies of a product. Before prescribing any product mentioned in this Register, healthcare professionals should consult prescribing information for the product approved in their country.

GSK Medicine: Orlistat	
Study No.: W3680604	
Title: A study to assess the pharmacologic equivalence of two orlistat dosage forms	
Rationale: Intended to confirm the bioequivalence of a new orlistat formulation to the marketed standard	
Phase: I	
Study Period: 6 February 2009 to 31 March 2009	
Study Design: Open-label, single-center, randomized, crossover, in-patient	
Centre: 1, Belfast, UK	
Indication: Fecal fat measurement	
Treatment: **Test Treatment:** Orlistat prototype, **Reference Treatment:** Orlistat marketed capsule.	
Objectives: To establish the bioequivalence of the orlistat prototype to the marketed orlistat capsule.	
Primary Outcome/Efficacy Variable: Total excretion of dietary fat in the faeces at steady-state (after the third day of treatment).	
Secondary Outcome/Efficacy Variable(s): NA	
Statistical Methods: Descriptive statistics were calculated and presented for the primary efficacy variable percent faecal fat (PFF). The primary analysis for establishing bioequivalence is two one-sided tests (TOST) based on the 90% CI of the ratio of geometric means of PFF. The acceptance range is (0.80, 1.25). Efficacy population is the per-protocol population – those subjects who completed the study without any major protocol violations or other problems that could affect the PFF data.	
Study Population: Overweight to obese adult subjects	
Number of Subjects:	
Planned, N	48
Randomised, N	48
Completed, n	46
Total Number Subjects Withdrawn, n	2
Withdrawn due to Adverse Events (AEs), n	0
Withdrawn due to Lack of Efficacy, n	0
Withdrawn for other reasons, n	2
Demographics	
N (Randomised)	48
Females: Males	6:42
Mean Age, years (SD)	32.2 (9.6)
Caucasian, n (%)	46 (95.8)

Primary Efficacy Results: Percent Faecal Fat after Day 3 of treatment (Per-Protocol Population)

Descriptive Statistics

Population		Prototype	Marketed	
			Low dose	High dose
Per Protocol	N Mean (SD) Median Range LSM 95%CI	44 19.8 (6.7) 19.0 9.0 – 36.6 19.4 17.3, 21.6	42 19.8(6.1) 20.6 4.7 – 34.7 20.2 18.0, 22.4	46 23.7 (8.5) 22.8 6.9 – 46.0 23.8 21.7, 25.9

Percent Faecal Fat: 90% CI of the Ratio of Means

Method / Data		Prototype	Marketed Low dose
	N Mean (SD) Median	44 19.8% (6.7) 19.0	42 19.8% (6.1) 20.6
TOST/ Log-transformed PFF	- Ratio of Geometric Means - 90% CI of ratio	0.96 0.87, 1.06	
Fieller's 90% CI / Original Scale Data	- Mean ratio - 90% CI (Fieller's CI)	0.96 0.88, 1.06	

Intent-to-Treat population had similar results.

Secondary Outcome Variable(s): none

Safety Results: Adverse events were attributed to a given treatment if they occurred after the first dose of that treatment and before the first dose of the next treatment, up to five days following the end of the study.

Treatment-related Adverse Events (Safety Population)

System Order Class / preferred term	Prototype (N=48) n (%)	nAE	Marketed Low dose (N=46) n (%)	nAE	Marketed High dose (N=48) n (%)	nAE
# Of Subjects With At Least 1 AE	5 (10.4)	9	5 (10.9)	6	9 (18.8)	18
Number Of Subjects With No AE	43 (89.6)		41 (89.1)		39 (81.3)	
Gastrointestinal Disorders	4 (8.3)	7	5 (10.9)	6	9 (18.8)	16
Abdominal Distension	3 (6.3)	3	4 (8.7)	4	3 (6.3)	3
Diarrhoea	0	0	1 (2.2)	1	2 (4.2)	6
Abdominal Pain Upper	0	0	0	0	5 (10.4)	5
Nausea	1 (2.1)	1	0	0	1 (2.1)	2
Constipation	1 (2.1)	1	1 (2.2)	1	0	0
Flatulence	2 (4.2)	2	0	0	0	0
Nervous System Disorders	2 (4.2)	2	0	0	1 (2.1)	2
Dizziness	1 (2.1)	1	0	0	1 (2.1)	1
Headache	1 (2.1)	1	0	0	1 (2.1)	1

n (%) = Number (percent) of subjects nAE = Number of adverse events

There were no Serious AEs in this study.