

**Table 64: Clinical evidence profile: Comparison 1.3. PERT + Omeprazole versus. PERT alone in adults**

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	PERT + Omeprazole	PERT alone	Relative (95% CI)	Absolute		
<b>Fat absorption (CFA) (follow-up 12 days; measured with: % of intake or consumed fat that is absorbed; Better indicated by higher values)</b>												
1 (Francisco 2002) <sup>2</sup>	randomised trials <sup>1</sup>	no serious risk of bias	no serious inconsistency	no serious indirectness	Not calculable <sup>3</sup>	Other <sup>4</sup>	9 Median: 87.40 (84.72 to 90.88) versus. 88.59 (79.01 to 93.46)	-	p≤0.05*	MODERATE	CRITICAL	
<b>Faecal fat excretion (FFE) (follow-up 4 weeks; measured with: % of intake, or consumed fat that is excreted; Better indicated by lower values) [low-dose PERT + omeprazole or placebo]</b>												
1 (Heijerman 1991) <sup>5</sup>	randomised trials <sup>1</sup>	serious <sup>6</sup>	no serious inconsistency	very serious <sup>7</sup>	Not calculable <sup>8</sup>	Other <sup>9</sup>	9 Median: 14 (6 to 32) versus. 20 (12 to 44)	-	p>0.05	VERY LOW	CRITICAL	
<b>Faecal fat excretion (FFE) (follow-up 4 weeks; measured with: % of intake, or consumed fat that is excreted; Better indicated by lower values) [high-dose PERT + omeprazole or placebo]</b>												
1 (Heijerman 1991) <sup>10</sup>	randomised trials <sup>1</sup>	serious <sup>6</sup>	no serious inconsistency	very serious <sup>7</sup>	Not calculable <sup>8</sup>	Other <sup>9</sup>	9 Median: 9 (4 to 25) versus. 18 (10 to 34)	-	p<0.01	VERY LOW	CRITICAL	
<b>Faecal fat excretion (FFE) (follow-up 4 weeks; measured with: % of intake, or consumed fat that is excreted; Better indicated by lower values)</b>												
1 (Heijerman 1993) <sup>11</sup>	randomised trials <sup>1</sup>	no serious risk of bias	no serious inconsistency	very serious <sup>12</sup>	Not calculable <sup>13</sup>	none	11 Median: 17 (4 to 45) versus. 20 (12 to 44)	-	p>0.05	LOW	CRITICAL	

Abbreviations: CFA: coefficient of fat absorption; CI: confidence interval; FFE: faecal fat excretion; PERT: pancreatic endocrine enzyme therapy

\* The paper provided raw data. Medians and p-values were calculated by the NGA technical team

1 Cross-over trial

2 Treatment details: Pancrease M10 or M16 + omeprazole 20 mg/day or placebo

3 Imprecision cannot be calculated from medians

4 Reporting bias not detected, but drugs were provided by the Pharmaceutical industry. Quality of evidence was downgraded by 1 due to small population (n=9).

5 Treatment details: PERT 2 capsules x 3 times per day + Omeprazole 20mg/day or placebo. Constituent enzymes per capsule 5000u lipase, 2900u lipase, 330u protease. Fat intake was not standardized.

6 The quality of the evidence was downgraded by 1 due to unclear randomization and concealment

7 The quality of the evidence was of evidence downgraded by 2 as this dosage is not used in current practice

8 Imprecision cannot be calculated from medians.

9 Reporting bias not detected. Evidence downgraded by 1 due to small sample size (n=9).

10 Treatment details: PERT 4 capsules x 3 times per day + Omeprazole 20mg/day or placebo. Constituent enzymes per capsule 5000u lipase, 2900u lipase, 330u protease. Fat intake was not standardized.

11 Treatment details: PERT 2 capsules x 3 times per day + Omeprazole 20mg/day or placebo. Constituent enzymes per capsule 5000u lipase, 2900u lipase, 330u protease. Fat intake was not standardized.

12 The quality of the evidence was of evidence downgraded by 2 as this dosage is not used in current practice

13 Imprecision cannot be calculated from medians