

Table 19: Clinical evidence profile: Dose A [10mg/5mg HC] vs Dose B [10mg/5mg/5mg HC]

Certainty assessment						Summary of findings		
		Inconsistency	Indirectness	Imprecision		Study event rates (%)		Anticipated absolute effects

Certainty assessment							Summary of findings				
Participants (studies) Follow-up	Risk of bias				Publication bias	Overall certainty of evidence	With Dose B [10mg/5mg/5mg HC]	With Dose A [10mg/5mg HC]	Relative effect (95% CI)	Risk with Dose B [10mg/5mg/5mg HC]	Risk difference with Dose A [10mg/5mg HC]
SF-36 - Physical sum scale (follow-up: 4 weeks; Scale from: 0 to 100)											
18 (1 RCT)	very serious ^a	not serious	not serious	very serious ^b	none	⊕○○○ Very low	18	18	-	The mean SF-36 - Physical sum scale was 40.7 points	MD 3.2 points higher (4.66 lower to 11.06 higher)
SF-36 - Psychological sum scale (follow-up: 4 weeks; Scale from: 0 to 100)											
18 (1 RCT)	very serious ^a	not serious	not serious	very serious ^c	none	⊕○○○ Very low	18	18	-	The mean SF-36 - Psychological sum scale was 46.4 points	MD 0.1 points lower (7 lower to 6.8 higher)
BSI Global Severity Index (follow-up: 4 weeks; Scale from: 0 to 100)											
18 (1 RCT)	very serious ^a	not serious	not serious	very serious ^d	none	⊕○○○ Very low	18	18	-	The mean BSI Global Severity Index was 58.1 points	MD 0.2 points lower (8.15 lower to 7.75 higher)
Satisfaction with medication (follow-up: 4 weeks; assessed with: 100 mm visual analog scale; Scale from: 0 to 100)											
18 (1 RCT)	very serious ^a	not serious	not serious	very serious ^e	none	⊕○○○ Very low	18	18	-	The mean satisfaction with medication was 56.6 points	MD 5.4 points lower (25.22 lower to 14.42 higher)
Sleepiness score 0700 (follow-up: 4 weeks; assessed with: Stanford Sleepiness Scale; Scale from: 0 to 7)											

Certainty assessment							Summary of findings				
18 (1 RCT)	very serious ^a	not serious	not serious	serious ^f	none	⊕○○○ Very low	18	18	-	The mean sleepiness score 0700 was 2.3 points	MD 0.2 points higher (0.02 lower to 0.42 higher)
Sleepiness score 1200 (follow-up: 4 weeks; assessed with: Stanford Sleepiness Scale; Scale from: 0 to 7)											
18 (1 RCT)	very serious ^a	not serious	not serious	very serious ^g	none	⊕○○○ Very low	18	18	-	The mean sleepiness score 1200 was 1.7 points	MD 0 points (0.17 lower to 0.17 higher)
Sleepiness score 1500 (follow-up: 4 weeks; assessed with: Stanford Sleepiness Scale; Scale from: 0 to 7)											
18 (1 RCT)	very serious ^a	not serious	not serious	very serious ^h	none	⊕○○○ Very low	18	18	-	The mean sleepiness score 1500 was 1.8 points	MD 0 points (0.17 lower to 0.17 higher)
Sleepiness score 1800 (follow-up: 4 weeks; assessed with: Stanford Sleepiness Scale; Scale from: 0 to 7)											
18 (1 RCT)	very serious ^a	not serious	not serious	not serious ⁱ	none	⊕⊕○○ Low	18	18	-	The mean sleepiness score 1800 was 2.1 points	MD 0.4 points lower (0.57 lower to 0.23 lower)
Sleepiness score 2200 (follow-up: 4 weeks; assessed with: Stanford Sleepiness Scale; Scale from: 0 to 7)											
18 (1 RCT)	very serious ^a	not serious	not serious	not serious ^j	none	⊕○○○ Very low	18	18	-	The mean sleepiness score 2200 was 3.4 points	MD 0.7 points lower (0.99 lower to 0.41 lower)

Explanations

- a. Downgraded by 2 increments for risk of bias (potential for measurement bias in patient-reported outcome, little information provided on deviations from intended interventions).
- b. Downgraded by 2 increments as confidence interval crossed both MIDs (+/- 2)
- c. Downgraded by 2 increments as confidence interval crossed both MIDs (+/- 3)
- d. Downgraded by 2 increments as confidence interval crossed both MIDs (+/- 6.45)
- e. Downgraded by 2 increments as confidence interval crossed both MIDs (+/- 13.65)
- f. Downgraded by 1 increment as confidence interval crossed 1 MID (+/- 0.16)
- g. Downgraded by 2 increments as confidence interval crossed both MIDs (+/- 0.145)
- h. Downgraded by 2 increments as confidence interval crossed both MIDs (+/- 0.12)
- i. No imprecision MID (+/- 0.15)
- j. No imprecision MID (+/- 0.25)