Clinical study summary (CSS)

CT registry ID#: NCT00139867
Study no.: SP780

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Proprietary drug name	**INN**	**Therapeutic area and indication(s)**
PARCOPA™	Carbidopa/levodopa	Parkinson's Disease

Name of Sponsor/company: UCB

Title of study:
A multicenter, open-label trial to assess subject preference of PARCOPA, carbidopa/levodopa orally disintegrating tablets, compared to conventional carbidopa/levodopa tablets in subjects with stable Parkinson's disease.

Investigator(s) (number only): 7

Study center(s) (number only): 7

Length of study:
Date first patient enrolled: 28 Jan 2004
Date last patient completed: 25 May 2004

Phase of development: Phase 3b

Abstract:
The objective of this trial was to assess subject preference for PARCOPA (carbidopa/levodopa orally disintegrating tablets [ODT]) vs conventional carbidopa/levodopa.

After Screening and a 7 (± 3) days Baseline period on a stable dose of conventional carbidopa/levodopa, eligible subjects received PARCOPA for 14 (±3) days at the same dose and schedule as their previous conventional carbidopa/levodopa medication.

Before and after the last Baseline dose of conventional carbidopa/levodopa, and before and after the last dose of PARCOPA, the unified Parkinson's disease rating scale was administered. Following the final dose of PARCOPA, subjects completed the global preference questionnaire regarding the preference for conventional carbidopa/levodopa or PARCOPA.

Number of subjects:	**Overall**
Planned, N:	54
Enrolled, N:	61
Intent to treat, N	60
Withdrawn due to adverse events, n (%):	0

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Safety outcomes:
- Summary of treatment emergent adverse events, deaths, other serious adverse events and certain other significant adverse events:

While more treatment-emergent adverse events (TEAEs) were reported during the 2-week PARCOPA period of the trial than during the 1-week conventional tablet Baseline period, relatively few TEAEs were reported overall and all were mild or moderate in severity. Only 1 subject experienced an SAE (pelvic fracture); this was not considered related to study medication. No subjects discontinued due to an AE and no subject died.

There were no apparent treatment-related trends in TEAEs. One subject experienced TEAEs of dry mouth and glossodynia during the PARCOPA period that were judged by the investigator to be study medication-related. Given the mode of administration of the medication, these events are of some interest.

Clinical laboratory test results, vital sign measurements and oral examination findings were unremarkable.

Treatment-emergent AEs:

Subjects with TEAEs ***(by Primary System Organ Class)***	**Treatment period**
	PARCOPA carbidopa/levodopa ODT (14 days) N=60
	n (%)
Cardiac disorders	*2 (3.3)*
Eye disorders	*1 (1.7)*
Gastrointestinal disorders	*3 (5.0)*
General disorders and administration site conditions	*1 (1.7)*
Infections and infestations	*1 (1.7)*
Injury, poisoning and procedural complications	*1 (1.7)*
Musculoskeletal and connective tissue disorders	*2 (3.3)*
Nervous system disorders	*3 (5.0)*
Psychiatric disorders	*1 (1.7)*
Respiratory, thoracic and mediastinal disorders	*1 (1.7)*

Death and other SAEs:

Death, n (%):	0
Subjects with SAEs, n (%):	1 (1.6)

Subjects with SAEs ***(by Primary System Organ Class)***	**Treatment period**	
	Conventional carbidopa/levodopa (7 days) N=61	**PARCOPA carbidopa/levodopa ODT (14 days) N=60**
	n (%)	
Fractured pelvis NOS	*0*	*1 (1.7)*

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Primary & secondary outcomes:

For each question on the global preference questionnaire, the percentage of subjects who preferred PARCOPA was larger than the percentage who preferred conventional tablets. For the overall measure of preference, 45% of subjects preferred PARCOPA, compared with 20.0% who preferred conventional tablets. The calculated difference between the two formulations in overall preference was 25.0% (p=0.0163).

Clear preferences were also seen in favor of PARCOPA in secondary variables, including concern about swallowing medication, self-consciousness about taking medication, convenience in complying with a dosing schedule, ease in daily activities, ease in taking medication at night and ease in several morning routines (such as taking other medication and eating breakfast).

The safety profiles of the two formulations of carbidopa/levodopa were comparable.

Publication reference(s) based on the study: none

Date of report: 19 Nov 2008