

# Abstract

Curr Med Res Opin. 2004 Sep;20(9):1377-84.

## **Preliminary observations on the use of propionyl-L-carnitine in combination with sildenafil in patients with erectile dysfunction and diabetes.**

Gentile V, Vicini P, Prigiotti G, Koverech A, Di Silverio F.

Department of Urology U Bracci, University La Sapienza, Rome, Italy.

**PURPOSE:** To investigate the efficacy and tolerability of oral propionyl-L-carnitine (PLC) plus sildenafil in men with erectile dysfunction (ED) and diabetes unresponsive to sildenafil monotherapy.

**MATERIALS AND METHODS:** Patients with medically documented ED of organic or mixed aetiology and diabetes (type 1 and 2) were randomised to receive oral PLC (2 g/day) plus sildenafil (50 mg twice weekly) (20 patients, Group 1) or sildenafil alone (20 patients, Group 2), in a double-blind, fixed-dose study. All patients had been previously treated unsuccessfully with a minimum of eight administrations of sildenafil. Efficacy was evaluated using the International Index of Erectile Function (IIEF) questionnaire: total score, subscores for questions 3 (Q3; achieving an erection) and 4 (Q4; maintaining an erection) and global efficacy question (GEQ: 'Has treatment improved your erections?'). Patients Event Logs were also used.

**RESULTS:** After 24 weeks of treatment, mean scores for IIEF Q3 and Q4 had improved significantly in patients of Group 1 (4.25 +/- 0.63 and 3.95 +/- 1.0) compared with Group 2 (2.9 +/- 0.71 and 2.7 +/- 0.96) ( $p < 0.01$ ). Moreover, the percentage of patients with improved erections (GEQ 68% vs. 23%) and successful intercourse attempts (76% vs. 34%) was significantly increased in Group 1 compared with Group 2 ( $p < 0.01$ ). Fourteen (70%) patients in Group 1 and four (20%) in Group 2 reported an increase in mean IIEF EF domain score of  $\geq 4$  ( $p < 0.01$ ). Treatments were well tolerated and no patient discontinued study medication. Two patients in Group 1 reported mild gastric pain.

**CONCLUSIONS:** Salvage therapy with PLC plus sildenafil was more effective than sildenafil in the treatment of ED in patients with diabetes refractory to sildenafil monotherapy.

PMID: 15383186