

Additional hypotensive effects following co-administration of non-selective alpha-blockers and phosphodiesterase-5-inhibitors

Final SPC and PIL wording agreed by PhVWP February 2009

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SPC

Section 4.4

"Concomitant use of phosphodiesterase-5-inhibitors (e.g. sildenafil, tadalafil, vardenafil) and /.../ may lead to symptomatic hypotension in some patients. In order to minimise the risk for developing postural hypotension the patient should be stable on the alpha-blocker therapy before initiating use of phosphodiesterase-5-inhibitors."

Section 4.5

"Phosphodiesterase-5-inhibitors (e.g. sildenafil, tadalafil, vardenafil) (see section 4.4)."
[Depending on the individual structure of the section 4.5, an introductory paragraph may have to be added; e.g.: "Concomitant use of phosphodiesterase-5-inhibitors (e.g. sildenafil, tadalafil, vardenafil) and /.../ may lead to symptomatic hypotension in some patients (see section 4.4).]

PIL

Section 2. Taking other medicines:

"Some patients who take alpha-blocker therapy for the treatment of high blood pressure or prostate enlargement may experience dizziness or light-headedness, which may be caused by low blood pressure upon sitting or standing up quickly. Certain patients have experienced these symptoms when taking drugs for erectile dysfunction (impotence) with alpha-blockers. In order to reduce the likelihood that these symptoms occur, you should be on a regular daily dose of your alpha-blocker before you start drugs for erectile dysfunction."