

Dopamine agonists and pathological gambling and increased libido

Agreed by the PhVWP in July 2006

The following SPC wording will be implemented in sections 4.4 and 4.8 for all dopamine agonists.

4.4 Special warnings and precautions for use

Pathological gambling, increased libido and hypersexuality have been reported in patients treated with dopamine agonists for Parkinson's disease, including <PRODUCT NAME>.

4.8 Undesirable effects

Patients treated with dopamine agonists for treatment of Parkinson's disease, including <PRODUCT NAME>, especially at high doses, have been reported as exhibiting signs of pathological gambling, increased libido and hypersexuality, generally reversible upon reduction of the dose or treatment discontinuation.

These changes should be reflected appropriately in the patient information leaflet.