

**Association of HMG-CoA Reductase Inhibitors<sup>1</sup> with the following safety concerns: sleep disturbances; memory loss; micturition disorders; sexual disturbance; depression; interstitial pneumopathy**

**Final SPC and PL wording agreed by the PhVWP in November 2009**

*Doc. Ref.: CMDh/PhVWP/006/2009  
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## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **Section 4.4 – Special warnings and precautions for use**

#### **Interstitial lung disease**

Exceptional cases of interstitial lung disease have been reported with some statins, especially with long term therapy (see section 4.8). Presenting features can include dyspnoea, non-productive cough and deterioration in general health (fatigue, weight loss and fever). If it is suspected a patient has developed interstitial lung disease, statin therapy should be discontinued.

### **Section 4.8 – Undesirable effects**

The following adverse events have been reported with some statins:

- Sleep disturbances, including insomnia and nightmares [where this is not already listed]
- Memory loss
- Sexual dysfunction [where this is not already listed]
- Depression
- Exceptional cases of interstitial lung disease, especially with long term therapy (see section 4.4)

## **PACKAGE LEAFLET**

### **Check with your doctor or pharmacist before taking [statin] if you:**

- Have severe respiratory failure

### **Possible side effects**

- Sleep disturbances, including insomnia and nightmares
- Memory loss
- Sexual difficulties
- Depression
- Breathing problems including persistent cough and/or shortness of breath or fever

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<sup>1</sup> atorvastatin; fluvastatin; lovastatin; pravastatin; rosuvastatin; simvastatin