

## **Rosuvastatin and the risk of diabetes mellitus**

**Final SPC wording Agreed by the PhVWP in May 2010**

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### **SUMMARY OF PRODUCT CHARACTERISTICS**

#### **Section 4.4**

##### *Diabetes Mellitus*

In patients with fasting glucose 5.6 to 6.9 mmol/L, treatment with rosuvastatin has been associated with an increased risk of diabetes mellitus (see section 4.8).

#### **Section 4.8**

##### *Endocrine disorders*

*Common:* diabetes mellitus<sup>1</sup>

<sup>1</sup> Observed in the JUPITER study (reported overall frequency 2.8% in rosuvastatin and 2.3% in placebo) mostly in patients with fasting glucose 5.6 to 6.9 mmol/L.