**HMG-CoA Reductase Inhibitors and safety the risk of new onset diabetes/impaired glucose metabolism**

**Final SmPC and PL wording agreed by PhVWP December 2011**

*Doc.Ref.: CMDh/PhVWP/042/2012 January 2012*

**SUMMARY OF PRODUCT CHARACTERISTICS**

**New Class Warnings**

**Section 4.4**

Diabetes Mellitus

Some evidence suggests that statins as a class raise blood glucose and in some patients, at high risk of future diabetes, may produce a level of hyperglycaemia where formal diabetes care is appropriate. This risk, however, is outweighed by the reduction in vascular risk with statins and therefore should not be a reason for stopping statin treatment. Patients at risk (fasting glucose 5.6 to 6.9 mmol/L, BMI>30kg/m2, raised triglycerides, hypertension) should be monitored both clinically and biochemically according to national guidelines.

**Section 4.8 – Atorvastatin**

Class Effects

• Sexual dysfunction

• Depression

• Exceptional cases of interstitial lung disease, especially with long term therapy (see section 4.4)

• Diabetes Mellitus: Frequency will depend on the presence or absence of risk factors (fasting blood glucose ≥ 5.6 mmol/L, BMI>30kg/m2, raised triglycerides, history of hypertension).

**Section 4.8 – Simvastatin**

Class Effects

• Sleep disturbances, including nightmares

• Memory loss

• Sexual dysfunction

• Diabetes Mellitus: Frequency will depend on the presence or absence of risk factors (fasting blood glucose ≥ 5.6 mmol/L, BMI>30kg/m2, raised triglycerides, history of hypertension).

**Section 4.8 - Fluvastatin**

Class Effects

• Sleep disturbances, including insomnia and nightmares,

• Memory loss

• Sexual dysfunction

• Depression

• Exceptional cases of interstitial lung disease, especially with long term therapy (see section 4.4)

• Diabetes Mellitus: Frequency will depend on the presence or absence of risk factors (fasting blood glucose ≥ 5.6 mmol/L, BMI>30kg/m2, raised triglycerides, history of hypertension).

**Section 4.8 – Lovastatin**

Class Effects

• […] ⃰

• Diabetes Mellitus: Frequency will depend on the presence or absence of risk factors (fasting blood glucose ≥ 5.6 mmol/L, BMI>30kg/m2, raised triglycerides, history of hypertension).

⃰ *Memory loss and sexual dysfunction will be amended in the CMD web pages according to assessor for lovastatin*

**Section 4.8 – Pravastatin**

Class Effects

• Nightmares

• Memory loss

• Depression

• Exceptional cases of interstitial lung disease, especially with long term therapy (see section 4.4)

• Diabetes Mellitus: Frequency will depend on the presence or absence of risk factors (fasting blood glucose ≥ 5.6 mmol/L, BMI>30kg/m2, raised triglycerides, history of hypertension).

**Section 4.8 - Pitavastatin**

Class Effects

• Sleep disturbances, including nightmares

• Memory loss

• Sexual dysfunction

• Depression

• Exceptional cases of interstitial lung disease, especially with long term therapy (see section 4.4)

• Diabetes Mellitus: Frequency will depend on the presence or absence of risk factors (fasting blood glucose ≥ 5.6 mmol/L, BMI>30kg/m2, raised triglycerides, history of hypertension).

**New Wording for Rosuvastatin SmPc.**

**Section 4.4**

Diabetes Mellitus

Some evidence suggests that statins as a class raise blood glucose and in some patients, at high risk of future diabetes, may produce a level of hyperglycaemia where formal diabetes care is appropriate. This risk, however, is outweighed by the reduction in vascular risk with statins and therefore should not be a reason for stopping statin treatment. Patients at risk (fasting glucose 5.6 to 6.9 mmol/L, BMI>30kg/m2, raised triglycerides, hypertension) should be monitored both clinically and biochemically according to national guidelines.

In the JUPITER study, the reported overall frequency of diabetes mellitus was 2.8% in rosuvastatin and 2.3% in placebo, mostly in patients with fasting glucose 5.6 to 6.9 mmol/L.

**Section 4.8**

*Endocrine disorders*

*Common:* diabetes mellitus1

1 Frequency will depend on the presence or absence of risk factors (fasting blood glucose ≥ 5.6 mmol/L, BMI>30kg/m2, raised triglycerides, history of hypertension).

**PACKAGE LEAFLET**

**Section 2**

While you are on this medicine your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.

**Section 4**

Diabetes. This is more likely if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure. Your doctor will monitor you while you are taking this medicine.