

Številka: 1382-12/2012  
Datum : 27. 2. 2012VSEM IMETNIKOM DOVOLJENJ ZA PROMET Z  
ZDRAVILI IZ SKUPINE ZAVIRALCEV  
REDUKTAZE HMG-CoAPtujška ulica 21  
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www.jazmp.si**Zahteva za predložitev spremembe tipa IB – dopolnitev povzetka glavnih značilnosti zdravila in navodila za uporabo za zdravila iz skupine zaviralcev reduktaze HMG-CoA**

Spoštovani,

Delovna skupina za farmakovigilanco (PhVWP) pri Evropski agenciji za zdravila EMA je v decembru 2011 pregledala podatke, povezane z uporabo zaviralcev reduktaze HMG-CoA, pridobljenih iz nekliničnih, kliničnih in epidemioloških preskušanj, literaturnih podatkov in spontanih poročil o povezavi s tveganjem za pojav diabetesa oziroma oslABLJENO presnovo glukoze. Na osnovi ocene podatkov je zaključila, da je treba informacije v povzetku glavnih značilnosti zdravila in navodilih za uporabo zdravil iz te skupine ustrezno dopolniti.

Imetnike dovoljenj za promet z zadevnimi zdravili, ki vloge za spremembo dovoljenja za promet še niso vložili, prosimo, da Javni agenciji RS za zdravila in medicinske pripomočke v skladu s Pravilnikom o dovoljenju za promet z zdravilom za uporabo v humani medicini (Uradni list RS, št. 109/2010) predložijo spremembo tipa IB. Vlogo za zadevna zdravila, ki so pridobila dovoljenje za promet po nacionalnem postopku, imetniki dovoljenj za promet predložijo najkasneje v 30 dneh ob objave obvestila, za zdravila, ki so pridobila dovoljenje za promet po mednarodnih postopkih, pa v skladu s časovnico referenčne države članice (RMS). Dodatne informacije in podporna dokumentacija v vlogi niso potrebne.

Rok za implementacijo spremembe je 13. maj 2012. Zdravila, izdelana po 13. avgustu 2012, morajo biti opremljena z novim navodilom za uporabo.

V nadaljevanju vam podajamo odobreno originalno besedilo spremembe, objavljeno je tudi na spletni strani Vodij agencij za zdravila <http://www.hma.eu/222.html>.

S spoštovanjem,

Pripravila:  
Katja Mohorčič, mag. lab. biomed.dr. Martina Cvelbar, mag. farm., spec.  
direktorica**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/m<sup>2</sup>, 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  $\geq$  5.6 mmol/L, BMI>30kg/m<sup>2</sup>, 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  $\geq$  5.6 mmol/L, BMI>30kg/m<sup>2</sup>, 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  $\geq$  5.6 mmol/L, BMI>30kg/m<sup>2</sup>, raised triglycerides, history of hypertension).

#### **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  $\geq$  5.6 mmol/L, BMI>30kg/m<sup>2</sup>, 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  $\geq$  5.6 mmol/L, BMI>30kg/m<sup>2</sup>, 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/m<sup>2</sup>, 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 mellitus<sup>1</sup>*

<sup>1</sup> *Frequency will depend on the presence or absence of risk factors (fasting blood glucose  $\geq$  5.6 mmol/L, BMI>30kg/m<sup>2</sup>, 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.