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Betreff: Pravastatin – hältige Arzneispezialitäten – Änderungen der Fach- und Gebrauchsinformationen aufgrund des HBD – PSUR Worksharing Projektes

Sehr geehrte Damen und Herren,

basierend auf der Evaluierung des PSURs im EU-HBD-worksharing Projekt (Verfahrensnummer: FR/H/PSUR/007/002) kommt es zu der Empfehlung, folgende Ergänzungen in die **Fach- und Gebrauchsinformation** aller Pravastatin – hältigen Arzneispezialitäten zur aufzunehmen.

Sollten diese bereits aufgenommen worden sein, betrachten Sie dieses Schreiben als gegenstandslos.

• Changes to the Product information

SPC

4.4 Special warnings and precautions for use

(...)

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 > 30 kg/m², raised triglycerides, hypertension) should be monitored both clinically and biochemically according to national guidelines.

4.5 Interaction with other medicinal products and other forms of interaction

(...) Vitamin K antagonists: As with other HMG-CoA reductase inhibitors, the initiation of treatment or dosage up-titration of Pravastatin in patients treated concomitantly with vitamin K antagonists (e.g. warfarin or another coumarin anticoagulant) may result in an increase in International Normalised Ratio (INR). Discontinuation or down-titration of Pravastatin may result in a decrease in INR. In such situations, appropriate monitoring of INR is needed.



4.8 Undesirable effects

(...) Skin and subcutaneous tissue disorders: dermatomyositis.

(...) Endocrine disorders

Diabetes mellitus

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

Patient leaflet

What you need to know before you take <Product name>

Other medicines and <Product name>:

If you are taking a drug used to treat and prevent formation of blood clots called "vitamine K antagonist", tell your doctor before taking <Product name> because the use of vitamin K antagonists concomitantly with <Product name> might increase the results of blood tests used to monitor the treatment with vitamin K antagonists.

4. Possible side effects

Overall list of possible side effects:

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

-Dermatomyositis (condition characterized by an inflammation of the muscles and the skin).

Oben angeführte Textabschnitte stellen eine Mindestanforderung dar, zusätzliche nationale Hinweise in diesen Abschnitten sind zu belassen.