Part VI Summary of the risk management plan

VI.1 Elements for summary tables in the EPAR

VI.1.1 Summary table of Safety concerns

Summary of safety concerns

Important identified risks	• Skeletal muscle effects: rhabdomyolysis, myopathy, myositis, myalgia, CK increases, myoglobinaemia, myoglobinuria • Hepatic effects: increased transaminases, hepatitis, jaundice • Diabetes mellitus • Asian population: increased plasma exposure • Drug Interactions: drug-drug interactions including gemfibrozil, ciclosporin, warfarin, other vitamin K antagonists and lopinavir/ritonavir • Use during pregnancy or lactation • Gynaecomastia • Memory loss • Stevens-Johnson syndrome • Pancreatitis
Important potential risks	• Acute kidney injury without rhabdomyolysis • Myasthenia gravis • Severe hepatic effects, including hepatic necrosis and fulminant hepatitis • Sexual dysfunction • Interstitial lung disease • Tendon disorders/tendon rupture
Missing information	• Use in children younger than 10 years • Drug-drug interactions with rosuvastatin in paediatric patients

VI.1.2 Table of on-going and planned additional PhV studies/activities in the Pharmacovigilance Plan

Not applicable.

VI.1.3 Summary of Post authorisation efficacy development plan

No study planned.

VI.1.4 Summary table of risk minimisation measures

Safety concern	Routine risk minimisation measures	Additional risk minimisation measures
Important identified risks		
Skeletal muscle effects: rhabdomyolysis, myopathy, myositis, myalgia, CK increases, myoglobinaemia, myoglobinuria	Included in SPC section(s) • 4.3 Contraindications • 4.4 Special warnings and precautions for use • 4.8 Undesirable effects	NA
Hepatic effects: increased transaminases, hepatitis, jaundice	Included in SPC section(s) • 4.4 Special warnings and precautions for use • 4.8 Undesirable effects	NA
Diabetes mellitus	Included in SPC section(s) • 4.4 Special warnings and precautions for use • 4.8 Undesirable effects	NA
Asian population: increased plasma exposure	Included in SPC section(s) • 4.2 Posology and method of administration • 4.3 Contraindications • 4.4 Special warnings and precautions for use	NA
Drug Interactions: drug-drug interactions including gemfibrozil, ciclosporin, warfarin, other vitamin K antagonists and lopinavir/ritonavir	Included in SPC section(s) • 4.3 Contraindications • 4.5 Interaction with other medicinal products and other forms of interaction	NA
Use during pregnancy or lactation	Included in SPC section(s) • 4.3 Contraindications • 4.6 Fertility, pregnancy and lactation	NA
Gynaecomastia	Included in SPC section(s) • 4.8 Undesirable effects	NA

Memory loss	Included in SPC section(s) • 4.8 Undesirable effects	NA

Stevens-Johnson Syndrome	Included in SPC section(s) • 4.8 Undesirable effects	NA
Pancreatitis	Included in SPC section(s) • 4.8 Undesirable effects	NA
Important potential risks		
Acute kidney injury without rhabdomyolysis	Currently available data do not support the need for risk minimisation measures.	NA
Myasthenia gravis	Currently available data do not support the need for risk minimisation measures.	NA
Severe hepatic effects, including hepatic necrosis and fulminant hepatitis	Currently available data do not support the need for risk minimisation measures.	NA
Sexual dysfunction	Included in SPC section(s) • 4.8 Undesirable effects	NA
Interstitial lung disease	Included in SPC section(s) • 4.8 Undesirable effects	NA
Tendon disorders/tendon rupture	Included in SPC section(s) • 4.8 Undesirable effects	NA
Missing information		
Use in children younger than 10 years	Included in SPC section(s) • 4.2 Posology and method of administration	NA
Drug-drug interactions with rosuvastatin in paediatric patients	Included in SPC section(s) • 4.5 Interaction with other medicinal products and other forms of interaction	NA

Rosuvastatin was first approved in 2002. A well-established safety profile based on more than a decade of post-authorisation experience with the originator product exists.

STADA Arzneimittel AG has an adequate Pharmacovigilance System in place.

Currently available data on acute kidney injury without rhabdomyolysis and myasthenia gravis do not support the need for risk minimisation measures. All other identified risks as well as interactions and missing information are sufficiently covered in the respective sections of the SPC. Therefore, no additional pharmacovigilance and risk minimisation activities are deemed necessary.