Part VI: Summary of the risk management plan

Summary of risk management plan for Zahron 5 mg, 10 mg, 20 mg, 40 mg film-coated tablets (rosuvastatin)

This is a summary of the risk management plan (RMP) for Zahron The RMP details important risks of Zahron, how these risks can be minimised, and how more information will be obtained about Zahron's risks and uncertainties (missing information).

Zahron 's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Zahron should be used.

I. The medicine and what it is used for

Zahron is authorised for adults, adolescents and children aged 6 years or older with primary hypercholesterolaemia (type IIa including heterozygous familial hypercholesterolaemia) or mixed dyslipidaemia (type IIb) as an adjunct to diet when response to diet and other non-pharmacological treatments (e.g. exercise, weight reduction) is inadequate.

Adults, adolescents and children aged 6 years or older with homozygous familial hypercholesterolaemia as an adjunct to diet and other lipid lowering treatments (e.g. LDL apheresis) or if such treatments are not appropriate.

Zahron is also authorized for prevention of major cardiovascular events in patients who are estimated to have a high risk for a first cardiovascular event (see Section 5.1), as an adjunct to correction of other risk factors.

It contains rosuvastatin as the active substance and it is administered orally.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Zahron, together with measures to minimise such risks and the proposed studies for learning more about Zahron's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

If important information that may affect the safe use of Zahron is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Zahron are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Zahron. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine);

List of important risks and missing information	
Important identified risks	• None
Important potential risks	• None

List of important risks and missing information	
Missing information	• None

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Zahron.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Zahron

Part VII: Annexes

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Annex 1 – EudraVigilance Interface

Not applicable.

Annex 2 – Tabulated summary of planned, ongoing, and completed pharmacovigilance study programme

Not applicable.

Annex 3 - Protocols for proposed, on-going and completed studies in the pharmacovigilance plan

Not applicable.

Annex 4 - Specific adverse drug reaction follow-up forms

Not applicable.

Annex 5 - Protocols for proposed and on-going studies in RMP part IV

Not applicable.

Annex 6 - Details of proposed additional risk minimisation activities (if applicable)

Not applicable.

Annex 7 - Other supporting data (including referenced material)

Not applicable.

Annex 8 – Summary of changes to the risk management plan over time

Version	Approval date Procedure	Change
0.2	At the time of authorisation procedure number: DK/H/3030/001-004/DC dd/mm/yyyy	Safety concern Important identified risks: • Rhabdomyolysis • Myopathy; myositis; myalgia; creatine kinase increases; myoglobinuria and myoglobinaemia (in the setting of rhabdomyolysis and myopathy) • Increased transaminases, hepatitis, jaundice • Pancreatitis • Memory loss • Proteinuria • Diabetes mellitus • Depression • Sleep disorders (including insomnia and nightmares) • Immune mediated necrotising myopathy (IMNM) • Thrombocytopenia/decreased platelet count • Stevens-Johnson syndrome / Toxic Epidermal Necrolysis (SJS / TEN) • Tendon disorders • Peripheral neuropathy • Drug interactions: ciclosporin, various protease inhibitor combinations with ritonavir, simeprevir, clopidogrel, gemfibrozil,

		eltrombopag, dronedarone, warfarin and other vitamin K antagonists, fusidic acid and ezetimibe Important potential risks: • Renal failure (including acute and chronic renal failure) and renal impairment • Hepatic failure: including hepatic necrosis and fulminant hepatitis • Amyotrophic lateral sclerosis (ALS) • Interstitial lung disease (ILD) • Drug-drug interactions with fibrates (other than gemfibrozil) Missing information: • Children < 6 years of age • Drug-drug interaction studies in the paediatric population
0.3	At the time of authorisation procedure number: DK/H/3030/001-004/DC dd/mm/yyyy	Safety concern Important identified risks: • None Important potential risks: • None Missing information: • None