Summary of risk management plan for ZENON/ZENON NEO (Rosuvastatin/Ezetimibe)

This is a summary of the RMP for ZENON/ZENON NEO. The RMP details important risks of ZENON/ZENON NEO how these risks can be minimized, and how more information will be obtained about ZENON/ZENON NEO's risks and uncertainties (missing information).

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

Important new concerns or changes to the current ones will be included in updates of ZENON/ZENON NEO's RMP.

VI.1. THE MEDICINE AND WHAT IT IS USED FOR

ZENON/ZENON NEO is authorized for primary hypercholesterolaemia/homozygous familial hypercholesterolaemia and prevention of cardiovascular events (see SmPC for the full indication). It contains rosuvastatin/ezetimibe as the active substance and it is given by oral route administration.

VI.2. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMIZE OR FURTHER CHARACTERIZE THE RISKS

Important risks of ZENON/ZENON NEO, together with measures to minimize such risks and the proposed studies for learning more about ZENON/ZENON NEO's risks, are outlined in the next sections.

Measures to minimize 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 authorized 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 (eg, with or without prescription) can help to minimize its risks.

Together, these measures constitute routine risk minimisation measures.

If important information that may affect the safe use of ZENON/ZENON NEO is not yet available, it is listed under "missing information" below.

VI.2.1. List of important risks and missing information

Important risks of ZENON/ZENON NEO are risks that need special risk management activities to further investigate or minimize 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 ZENON/ZENON NEO. 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 (eg, on the long-term use of the medicine);

Table 1 - List of important risks and missing information

Important identified risks	Rhabdomyolysis/myopathy including immune-mediated necrotizing myopathy Abnormal liver function: Increased transaminases, jaundice, hepatitis
Important potential risks	None
Missing information	Use in pregnancy Use during lactation

VI.2.2. Summary of important risks

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

VI.2.3. Post-authorization development plan

VI.2.3.1. Studies which are conditions of the marketing authorization

Not applicable.

VI.2.3.2. Other studies in post-authorization development plan

There are no studies required for ZENON/ZENON NEO.

REFERENCES

None