PART VI SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of the Risk Management Plan for Qaialdo 10 mg/mL oral suspension

This is a summary of the risk management plan (RMP) for Qaialdo 10 mg/mL oral suspension. The RMP details important risks of Qaialdo 10 mg/mL oral suspension and how more information will be obtained about Qaialdo 10 mg/mL oral suspension 's risks and uncertainties (missing information).

There are no identified risks, potential risks and missing information for Qaialdo 10 mg/mL oral suspension which are considered important for further characterization.

Qaialdo 10 mg/mL oral suspension's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Qaialdo 10 mg/mL oral suspension should be used.

This summary of the RMP for Qaialdo 10 mg/mL oral suspension should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all of which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Qaialdo 10 mg/mL oral suspension's RMP.

I. The Medicine and What it is Used For

The medicine contains spironolactone as the active substance, and it is given by mouth. Qaialdo 10 mg/ml oral suspension is indicated in the management of refractory oedema associated with congestive cardiac failure; hepatic cirrhosis with ascites and oedema, malignant ascites, nephrotic syndrome, diagnosis and treatment of primary aldosteronism, essential hypertension.

Neonates, children and adolescents should only be treated under guidance of a paediatric specialist, as there is limited paediatric data available.

Further information about the evaluation of Qaialdo 10 mg/mL oral suspension's benefits can be found in Qaialdo 10 mg/mL oral suspension's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage https://www.ema.europa.eu/en/medicines/human/EPAR/qaialdo.

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Risks of Qaialdo 10 mg/mL oral suspension, together with measures to minimise such risks and the proposed studies for learning more about Qaialdo 10 mg/mL oral suspension's risks, are outlined below.

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

- 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.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, included in periodic safety update reports (PSURs) as applicable, so that immediate action can be taken as necessary. These measures constitute ***routine pharmacovigilance activities***.

II.A List of Important Risks and Missing Information

Important risks of Qaialdo 10 mg/mL oral suspension are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered/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 Qaialdo 10 mg/mL oral suspension. 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 risk	None
Important potential risk	None
Missing Information	None

II.B Summary of Important Risks

The safety information in the proposed Product Information is aligned to the reference medicinal product and there are no safety concerns for Qaialdo 10 mg/mL oral suspension.

II.C Post-Authorisation Development Plan

II.C.1 Studies Which are Conditions of the Marketing Authorisation

There are no studies which are conditions for the marketing authorisation or specific obligation of Qaialdo 10 mg/mL oral suspension.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Qaialdo 10 mg/mL oral suspension.