Part VI: Summary of activities in the risk management plan by product

VI.1 Elements for summary tables in the EPAR

VI.1.1 Summary table of Safety concerns

Summary of safety concerns	
Important identified risks	• Hypersensitivity reactions • Calcification of gallstones
Important potential risks	• Impaired liver function
Important missing information	• Lactating women • Pregnant women

VI.1.2 Table of on-going and planned studies in the Post-authorisation Pharmacovigilance Development Plan

None.

VI.1.3 Summary of Post authorisation efficacy development plan

None.

VI.1.4 Summary table of Risk Minimisation Measures

Safety concern	**Routine risk minimisation measures**	**Additional risk minimisation measures**
• Hypersensitivity reactions	Covered under section 4.3 of the SmPC.	-
• Calcification of gallstones	Covered under section 4.8 of the SmPC.	-
• Impaired liver function	Covered under section 4.4 and 4.8 of the SmPC.	-
• Lactating women	Covered under section 4.6 of the SmPC.	-
• Pregnant women	Covered under section 4.6 of the SmPC.	-

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Indication:

For the dissolution of cholesterol gallstones in the gall bladder. The gallstones should be x-ray negative and have a diameter less than 15 mm. The gall bladder must be functioning despite the gallstone(s).

Primary biliary cirrhosis (PBC) stages I – III.

Paediatric population

Hepatobiliar disorder associated with cystic fibrosis in children aged 6 years to less than 18 years.

The occurrence of the listed indications have not been specifically investigated by Orifarm Generics A/S. The listed indications are not judged to be specific for any population or pattern.

No further details as RMP Part II module is not applicable for generics and this section is an abbreviated version of this section.

VI.2.2 Summary of treatment benefits

Taking into account the published information on the use and dosage of UDCA, it can be concluded that the use of this medicinal product in the proposed indications, i.e. dissolution of gallstones and treatment of PBC, and according to the dosage recommendations given in the SmPC is fully justified. Safety and efficacy of UDCA in adults with gallstone and PBC is sufficiently evident from its approved clinical use. Hence, the risk-to-benefit ratio of UDCA remains positive.

(Module 2.5.6 conclusion of UDCA dossier)

VI.2.3 Unknowns relating to treatment benefits

Not applicable.

VI.2.4 Summary of safety concerns

Summary of safety concerns	
Important identified risks	• Hypersensitivity reactions • Calcification of gallstones
Important potential risks	• Impaired liver function
Important missing information	• Lactating women • Pregnant women

VI.2.5 Summary of risk minimisation measures by safety concern

Routine Pharmacovigilance is used for all safety concerns.
There are no specific risk minimisation measures.

The Summary of Product Characteristics and the Package leaflet for Ursodiol can be found in Annex 2.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

Not applicable.

VI.2.7 Summary of changes to the Risk Management Plan over time

Not applicable as this is the initial Risk Management Plan.

Major changes to the Risk Management Plan over time

Version	Date	Safety Concerns	Comment
	At time of authorisation dd/mm/yyyy	Identified Risks Potential Risks Missing information	
-	-	-	-