6.2 Elements for a Public Summary

6.2.1 Overview of disease epidemiology

Zorette 75 µg tablets is indicated for treatmen of:

- Oral contraception

6.2.2 Summary of treatment benefits

The marketing authorization applications request for *Zorette* is for generic medicinal products. Their treatment benefits are the same as proposed by the innovator. This medicinal product contains desogestrel as active substance, which is a derivate of natural progesterone, structurally related to levonorgestrel. It has been used for contraception for decades. The safety of desogestrel has been evaluated in clinical investigations frequently and sufficiently. Only limited information on acute toxixity of desogestrel is available.

6.2.3 Unknowns relating to treatment benefits

The marketing authorization applications request for *Zorette* 75 mg tablets*soft* from CampusPharma are for generic medicinal products. The treatment benefits are well established and are in accordance with the treatment benefits proposed by the originator.

6.2.4 Summary of safety concerns

The safety ptofile of the active substance of Zorette 75 µg tablets is well characterised through extensive non-clinical, clinical and post-marketing experience.

Safety concern	Planned action	Additional risk minimisation measures
Increasing risk for breast cancer with increasing age	Routine pharmacovigilance, including ICR, screening of literature, PBRER and ongoing signal detection	Information is given in section 4.4 of the SPC
Effects on liver / liver cancer	Routine pharmacovigilance, including ICR, screening of literature, PBRER and ongoing signal detection	Information is given in section 4.4 of the SPC
Venous thromboembolism	Routine pharmacovigilance, including ICR, screening of literature, PBRER and ongoing signal detection	Information is given in section 4.4 of the SPC

The following table summarizes important identified risk:

6.2.5 Summary of additional risk minimisation activities by safety concern

No additional risk minimization measures are planned. The Marketing Authorisation Holder considers that the proposed routine risk minimisation activities address the information in order to minimize the risk of *Zorette 75 µg tablets.*

Nevertheless, any changes in the risk-benefit profile in the use of progesterone which may require risk minimization activities will be presented in future updates of the EU-RMP.

6.2.6 Planned post-authorisation development plan

Besides routine pharmacovigilance activities, there are no planned activities in terms of efficacy studies and further investigation of safety concerns.

6.2.7 Summary of changes to the Risk Management Plan over time

Not applicable.
This is the first EU-RMP for *Zorette 75 µg tablets.*