Part III: Pharmacovigilance Plan (including post-authorisation safety studies)

III.1 Routine pharmacovigilance activities

As a part of the routine pharmacovigilance activities, new safety data will be closely monitored for the events confusion, hallucination, dyspnoea and use in pregnancy/lactation are evaluated to further characterise these risks.

Any new data leading to a change in the benefit-risk profile of the product will immediately be notified to the competent authorities.

III.2 Additional pharmacovigilance activities

No additional pharmacovigilance activities are required for the product.

III.3 Summary table of additional pharmacovigilance activities

Not applicable