Summary of risk management plan for Buprenorphine/Naloxone Mylan (Buprenorphine/Naloxone)

This is a summary of the risk management plan (RMP) for Buprenorphine/Naloxone Mylan. The RMP details important risks of buprenorphine / naloxone, how these risks can be minimised, and how more information will be obtained about buprenorphine / naloxone's risks and uncertainties (missing information).

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

I. The medicine and what it is used for

Buprenorphine/Naloxone Mylan is authorised for substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. The intention of the naloxone component is to deter intravenous misuse. Treatment is intended for use in adults and adolescents over 15 years of age who have agreed to be treated for addiction. It contains buprenorphine / naloxone as the active substance and it is given by sublingual route.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Buprenorphine/Naloxone Mylan, together with measures to minimise such risks are outlined below.

Measures to minimise 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 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 public (e.g. with or without prescription) can help to minimises its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse events is collected continuously and regularly analysed, including PSUR assessment, 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 Buprenorphine/Naloxone Mylan are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered to/taken by patients. 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 Buprenorphine/Naloxone Mylan. 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/use in special patient populations etc.);

Table 1 Part VI: Summary of safety concerns

List of important risks and missing information	
Important identified risks	➢ Abuse, misuse and diversion ➢ Use in patients with hepatic impairment ➢ Hepatic disorders ➢ Drug withdrawal syndrome ➢ Use during pregnancy and lactation leading to opioid toxicity or withdrawal in the child.
Important potential risks	➢ 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.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

Not applicable.

II.C.2 Other studies in post-authorisation development plan

Not applicable.