Part VI: Summary of the risk management plan

Summary of risk management plan for *Buprenorphine G.L. Sublingual tablets* (buprenorphine)

This is a summary of the risk management plan (RMP) for *Buprenorphine G.L. Sublingual tablets*. The RMP details important risks of *Buprenorphine G.L. Sublingual tablets*, how these risks can be minimised, and how more information will be obtained about *Buprenorphine G.L. Sublingual tablets'* risks and uncertainties (missing information).

Buprenorphine G.L. Sublingual tablets' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how *Buprenorphine G.L. Sublingual tablets* should be used.

Important new concerns or changes to the current ones will be included in updates of *Buprenorphine G.L. Sublingual tablets'* RMP.

I. The medicine and what it is used for

Buprenorphine G.L. Sublingual tablets are authorised for the symptomatic treatment of severe and very severe pain conditions, e.g. after operations and injuries, in heart attacks and tumours, which cannot be adequately treated with non-opioid analgesics.

Buprenorphine G.L. Sublingual tablets should not be used for headaches, toothaches, migraines or other painful conditions that can be treated with peripherally acting analgesics and/or spasmolytics.

Buprenorphine G.L. Sublingual tablets contain buprenorphine as the active substance and are given via sublingual application. *Buprenorphine G.L. Sublingual tablets* are available in strengths of 0.2 mg and 0.4 mg.

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

Important risks of *Buprenorphine G.L. Sublingual tablets*, together with measures to minimise such risks and the proposed studies for learning more about *Buprenorphine G.L. Sublingual tablets'* 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 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, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of *Buprenorphine G.L. Sublingual tablets* is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of *Buprenorphine G.L. Sublingual tablets* are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely 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 *Buprenorphine G.L. Sublingual tablets*. 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 risks	- Respiratory depression - Drug dependence and withdrawal - Abuse, misuse and diversion - Fatal overdose - Paediatric intoxication - Use during pregnancy and lactation (effects on newborn and infant) - Use in patients with severe hepatic impairment - CNS depression
Important potential risks	- Medication error
Missing information	- Elderly patient > 65 years old - Children < 15 years old

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

There are no studies which are conditions of the marketing authorisation or specific obligation of *Buprenorphine G.L. Sublingual tablets*.

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

There are no studies required for *Buprenorphine G.L. Sublingual tablets*.