Part IV: Plans for post-authorisation efficacy studies

Not applicable.

Part V: Risk minimisation measures (including evaluation of the effectiveness of risk minimisation activities)

Risk Minimisation Plan

The safety information in the proposed product information is aligned to the reference medicinal product.

Sections V.1 – V.3 is not applicable.

Part VI: Summary of the risk management plan for Buprefarm

This is a summary of the risk management plan (RMP) for Buprefarm. The RMP details no important risks of Buprefarm and no missing information.

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

I. The medicine and what it is used for

Buprefarm is authorised for relief of moderate, long-lasting pain that requires the use of a strong painkiller. It contains buprenorphine the active substances and it is given in patches to place on the skin.

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

Important risks of Buprefarm together with measures to minimise such risks and the proposed studies for learning more about Buprefarm's risks, are outlined below.

- Product information including warnings, precautions, and advice on correct use. Package leaflet is enclosed in the package and the Summary of Product Characteristics (and Package Leaflet) are published on the webpage of the Swedish, Danish, Norwegian and Finnish Medicines Agencies.
- The medicine's is prescription only medicine and must be prescribed by a doctor.

Together, these measures constitute *routine risk minimisation* measures.

If important information that may affect the safe use of Buprefarm is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Buprefarm 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 Buprefarm. 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);

Summary of safety concerns	
Important identified risks	• Respiratory depression • Accidental overdose • Drug withdrawal • Drug abuse and dependence
Important potential risks	• Medication error
Missing information	• Use in pregnant and breastfeeding patients • Paediatric use

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 Buprefarm.

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

There are no studies required for Buprefarm