sRMP

Libroxar

NL/H/4400/001-002/DC

Part VI: Summary of the risk management plan

Summary of risk management plan for Buloxx® (BUPRENORPHINE/ NALOXONE)

This is a summary of the risk management plan (RMP) for Buloxx®. The RMP details important risks of Buloxx®, and how more information will be obtained about Buloxx®'s risks and uncertainties (missing information).

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

I. The medicine and what it is used for

Buloxx® is authorized as 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 (see SmPC for the full indication). It contains BUPRENORPHINE and NALOXONE as active substances and it is given by oral sublingual route as tablets containing 2 mg/ 0,5 mg buprenorphine/ naloxone or 8 mg/ 2 mg buprenorphine/ naloxone respectively.

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

Important risks of Buloxx®, together with measures to minimise such risks and the proposed studies for learning more about Buloxx®'s 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.

II.A List of important risks and missing information

Important risks of Buloxx® are risks that need special risk management activities to further investigate or minimize 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 Buloxx®. 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	• Fatal overdose
	  ○ Severe respiratory failure (mechanism for death by overdose)
	  ○ Use in patients with alcoholism/ delirium tremens
	• Misuse and/or abuse (injection/ intranasal/pediatric use)
	• Hepatitis, hepatic events, use in patients with hepatic failure
	• Dependence
	• Drug withdrawal syndrome
	• Use during pregnancy, and lactation (effects on newborn and infant)
	• CNS depression (effects on driving ability)
	• Allergic reactions

Important potential risks	• Use in patients with head injury and intracranial pressure • Peripheral oedema
Missing information	• Elderly patients >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 Buloxx®.

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

There are no studies required for Buloxx®.