Part VI: Summary of the risk management plan

Summary of risk management plan for

Bupropion 150 mg, 300 mg modified release tablets (bupropion hydrochloride)

This is a summary of the risk management plan (RMP) for Bupropion 150 mg 300 mg modified release tablets. The RMP details important risks of Bupropion 150 mg 300 mg modified release tablets and how more information will be obtained about Bupropion 150 mg 300 mg modified release tablets's risks and uncertainties (missing information).

Bupropion 150 mg 300 mg modified release tablets's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Bupropion 150 mg 300 mg modified release tablets should be used.

I. The medicine and what it is used for

Bupropion 150 mg 300 mg modified release, is indicated for the treatment of major depressive episodes. It contains bupropion hydrochloride as the active substance and it is given by the oral route.

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

Important risks of Bupropion 150 mg 300 mg modified release tablets, together with measures to minimise such risks and the proposed studies for learning more about Bupropion 150 mg 300 mg modified release tablets'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.**

II.A List of important risks and missing information

Important risks of Bupropion 150 mg 300 mg modified release tablets are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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 Bupropion 150 mg 300 mg modified release 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	**None**
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[2].

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 Bupropion 150 mg 300 mg modified release tablets.

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

There are no studies required for Bupropion 150 mg 300 mg modified release tablets.