Part VI: Summary of the risk management plan

Summary of risk management plan for Vortioxetine Vivanta/ Vortioxetine Vivanta Generics 5 mg, 10 mg, 15 mg and 20 mg film-coated tablets (Vortioxetine)

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

Vortioxetine´s Summary of Product Characteristics (SmPC) and its Package Leaflet (PL) give essential information to healthcare professionals and patients on how Vortioxetine should be used.

Important new concerns or changes to the current ones will be included in updates of Vortioxetine´s RMP.

I. The medicine and what it is used for

Vortioxetine is authorised for the treatment of major depressive episodes in adults.

It contains vortioxetine as the active substance and are given by oral route of administration.

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

Important risks of Vortioxetine, 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 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 Vortioxetine is not yet available, it is listed under 'missing information below'.

II.A List of important risks and missing information

Important risks of Vortioxetine are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered.

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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 Vortioxetine. 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	• Serotonin syndrome
Important Potential risks	• None
Missing Information	• Off-label 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 obligations of Vortioxetine.

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

There are no studies required for Vortioxetine.

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