Summary of risk management plan for Nortriptyline RIA 10 mg, 25 mg and 50 mg tablet (Nortriptyline)

This is a summary of the risk management plan (RMP) for Nortriptyline RIA 10 mg, 25 mg and 50 mg tablet. The RMP details important risks of Nortriptyline RIA 10 mg, 25 mg and 50 mg tablet, routine risk minimisation activities recommending specific clinical measures to address the risk. Routine Pharmacovigilance will be used to ensure that all suspected adverse reactions to Nortriptyline are collected, collated and reported to the agency in accordance with the regulatory requirements; either as expedited reports or PSURs as appropriate.

Continuous monitoring of safety profile including signal detection and analysis will be carried out to determine if any updating of labelling is required and/or liaison with the agency for risks and uncertainties (missing information).

Nortriptyline RIA 10 mg, 25 mg and 50 mg tablet summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Nortriptyline RIA 10 mg, 25 mg and 50 mg tablet should be used.

I. The medicine and what it is used for

Nortriptyline RIA 10 mg, 25 mg and 50 mg tablet indication:

- For the treatment of major depressive episodes in adults.

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

Important risks of Nortriptyline, together with measures to minimise such risks and the proposed studies for learning more about Nortriptyline 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, including PSUR assessment 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 Nortriptyline 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 Nortriptyline RIA 10 mg, 25 mg and 50 mg tablet. 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	• None
Summary of safety concerns	
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.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

Not applicable

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

Not applicable