

V.3 Summary of risk minimisation measures

There are no safety concerns for nortriptyline. The safety information in the proposed Product Information is deemed to be sufficient.

Part VI: Summary of the risk management plan

Summary of the RMP for Noritren (nortriptyline)

This is a summary of the RMP for Noritren. The RMP details important risks of Noritren and how more information will be obtained about Noritren's risks and uncertainties (missing information).

Considering that nortriptyline is widely used and has been marketed for decades, no relevant gaps in knowledge which may affect its favourable risk-benefit profile has been identified. There is no expectation that any additional pharmacovigilance activities can further characterize the safety profile of this product or that any additional risk minimization measures can substantially minimize the risk.

The medicinal product's (SmPC) and its package leaflet (PL) give essential and adequate information to healthcare professionals and patients on how it should be used.

I. The medicine and what it is used for

Noritren is authorised in Finland for the treatment of depression of unipolar and bipolar type, and may be tried in reactive, neurotic and symptomatic depression treatment.

It contains nortriptyline as the active substance and it is given by oral route.

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

Considering that nortriptyline is widely used and has been marketed for decades, no relevant information (from market introduction to 31-Mar-2019) which may affect its favourable risk-benefit profile has been identified. There is no expectation that any additional pharmacovigilance activities can further characterize the safety profile of this product or that any additional risk minimization measures can substantially minimize the risk. This assessment is supported by the latest PSUR, covering the period from 01-Apr-2018 to 31-Mar-2019 of the current Lundbeck product for the active substance nortriptyline.

The routine pharmacovigilance practices as well as routine risk minimization measures are deemed sufficient.

Routine 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 and packaging design — with important information to ensure that the medicine is used correctly;
- The medicine's legal status — the medicine is supplied to the patient with prescription only, which helps to minimise its risks.

Additionally, 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 Noritren are risks that need special risk management activities, 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 evidence of a link with the use of concerned product. 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 yet been established. 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).

No RMP is in place for Lundbeck's ERP (Noritren).

In accordance with the GVP Module V (Rev 2) and as endorsed by PRAC in procedure PSUSA/00002192/201803, no identified or potential risk neither missing information are included as safety concerns.

Table 3: Summary of safety concerns

Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

The safety information in the proposed national SmPC of Noritren is aligned to the Lundbeck's ERP (Noritren). No new risk is anticipated for the patient since the medication will be used in line with the posology and method of administration described in the SmPC and PL.

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 Noritren.

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

There are no studies required for Noritren.