PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for escitalopram.

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

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

I. The medicine and what it is used for

Escitalopram is authorised and indicated for treatment of major depressive episodes, panic disorder with or without agoraphobia, social anxiety disorder (social phobia), generalised anxiety disorder and obsessive-compulsive disorder.

It contains escitalopram as the active substance and it is given by 5, 10, 15 & 20 mg film-coated tablets for oral administration.

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

Important risks of escitalopram, 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 public (e.g. with or without prescription) can help to minimises its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse events is collected continuously and is regularly analysed, including in PSUR assessment (include PSUR statement only if product has PSUR requirements as per EURD list), 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 escitalopram is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of escitalopram are those risks that need special risk management activities to further investigate or minimise them, so that the medicinal product can be safely administered to patients. 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 escitalopram. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but the definite causal 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/use in special patient populations etc.);

Table 4 Part VI: Summary of safety concerns

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.

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 escitalopram.

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

There are no studies required for escitalopram.