Part VI: Summary of the risk management plan

Summary of risk management plan for Cipralex (escitalopram)

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

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

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

I. The medicine and what it is used for

Cipralex is authorised for the treatment of: major depressive episodes; panic disorder with or without agoraphobia; social anxiety disorder (social phobia); generalised anxiety disorder; obsessive-compulsive disorder and treatment of premenstrual dysphoric disorder (only Premalex). (see SmPC for the full indication). It contains escitalopram as the active substance and it is given by film-coated tablets (5, 10, 15 and 20 mg), orodispersible tablets (10 and 20 mg) or oral drops (20 mg/ml).

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

Important risks of Cipralex, together with measures to minimise such risks and the proposed studies for learning more about Cipralex'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 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 the *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*.

If important information that may affect the safe use of Cipralex is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Cipralex 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 Cipralex. 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	Electrocardiogram QT prolonged
Important potential risks	None
Missing information	Use during pregnancy and lactation

II.B Summary of important risks

Important Identified Risk: Electrocardiogram QT prolonged	
Evidence for linking the risk to the medicine	Clinical trial data (thorough QT study); literature.
Risk factors and risk groups	Age, female gender, bradycardia, heart failure, recent cardioversion, prolonged QT interval, electrolyte abnormalities, hepatic/renal dysfunction, genetic predisposition, structural heart disease/LV dysfunction, and starvation or obesity.
Risk minimisation measures	<u>Routine risk minimisation measures</u>: SmPC section 4.8 (Undesirable effects) and in section 4.9 (Overdose). No specific clinical measures to address the risk are recommended in the Core SmPC. <u>Additional risk minimisation measures</u>: No risk minimisation measures.

Missing information: Use during pregnancy and lactation	
Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.6 (Fertility, pregnancy and lactation). Product should not be used during pregnancy, unless clearly needed. Breast-feeding while treated with product is not recommended. Additional risk minimisation measures: No risk minimisation measures

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 Cipralex.

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

There are no studies required for Cipralex.