Summary of risk management plan for ESCITALOPRAM ORION 5 MG, 10 MG 15 MG AND 20 MG FILM-COATED TABLETS (ESCITALOPRAM) Orion Corporation

Date: 14-10-2021, VERSION 3

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

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

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

I. The medicine and what it is used for

Escitalopram Orion is indicated for the treatment of

- major depressive episodes
- panic disorder with or without agoraphobia
- social anxiety disorder (social phobia)
- generalised anxiety disorder
- obsessive-compulsive disorder

It contains escitalopram as the active substance and it is given by mouth.
See SmPC for the full information.

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

II.A List of important risks and missing information

This product has no safety concerns requiring additional pharmacovigilance actions or additional risk minimisation activities.
Safety concerns are adequately addressed in the product information.

II.B Summary of important risks

The safety information in the product information is aligned to the reference medicinal product.

II.C Post-authorisation development plan

There are no studies required for Escitalopram Orion.