Summary of risk management plan for Venlafaxin Orion 225 mg prolonged-release capsules, hard (venlafaxine) Orion Corporation

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

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

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

I. The medicine and what it is used for

Venlafaxin Orion is indicated in:

- treatment of major depressive episodes
- prevention of recurrence of major depressive episodes
- treatment of generalised anxiety disorder
- treatment of social anxiety disorder
- treatment of panic disorder, with or without agoraphobia.

It contains venlafaxine as the active substance and it is given by mouth.

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

Important risks of Venlafaxin Orion, together with measures to minimise such risks and the proposed studies for learning more about Venlafaxin Orion'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 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 so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

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.

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

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

There are no studies required for Venlafaxin Orion.