

Summary of risk management plan for Duloxetine Orion 30 mg and 60 mg hard gastro- resistant capsules (Duloxetine) Orion Corporation

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

I. The medicine and what it is used for

Duloxetine Orion is authorised for treatment of major depressive disorder, diabetic peripheral neuropathic pain, and generalised anxiety disorder (see SmPC for the full indication). It contains duloxetine 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 Duloxetine Orion, together with measures to minimise such risks and the proposed studies for learning more about Duloxetine 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, 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 Duloxetine Orion is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Duloxetine Orion 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 Duloxetine Orion. 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	Suicidality
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

There are no studies required for Duloxetine Orion.