

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Duloxetine STADA, Duloxetine STADA Arzneimittel AG, Duloxetine STADA AG (Duloxetine)

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

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

Important new concerns or changes to the current ones will be included in updates of Duloxetine STADA's, Duloxetine STADA Arzneimittel AG's and Duloxetine STADA AG's RMP.

I. The medicine and what it is used for

Duloxetine STADA and Duloxetine STADA AG (30 mg, 45 mg, 60 mg, 90 mg and 120 mg gastro-resistant capsules) is authorised for the treatment of major depressive disorder, the treatment of diabetic peripheral neuropathic pain and the treatment of generalised anxiety disorder; Duloxetine STADA Arzneimittel AG (20 mg and 40 mg gastro-resistant capsules) is authorised for SUI (see SmPCs for the full indications). It contains duloxetine as the active substance and it is given by oral route of administration.

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

Important risks of Duloxetine STADA, Duloxetine STADA Arzneimittel AG and Duloxetine STADA AG, together with measures to minimise such risks and the proposed studies for learning more about Duloxetine STADA, Duloxetine STADA Arzneimittel AG and Duloxetine STADA AG 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.

II.A List of important risks and missing information

Important risks of Duloxetine STADA, Duloxetine STADA Arzneimittel AG and Duloxetine STADA AG 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 STADA, Duloxetine STADA Arzneimittel AG and Duloxetine STADA AG. 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 risk and missing information	
Important Identified Risks	Suicidality
Important Potential Risks	None
Missing Information	None

II.B Summary of important risks

Important Identified Risks: Suicidality	
Risk minimisation measures	<u>Routine risk minimisation measures</u> <u>30 mg, 45 mg, 60 mg, 90 mg and 120 mg gastro-resistant capsules</u> SmPC Section 4.4 Special warnings and precautions for use, 4.8 Undesirable effects, 5.1 Pharmacodynamic properties. <u>20 mg and 40 mg gastro-resistant capsules</u> SmPC Section 4.4 Special warnings and precautions for use, 4.8 Undesirable effects. Prescription only medicine <u>Additional risk minimisation measures</u> None
Important Potential Risks: None	
Missing Information: None	

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 for Duloxetine STADA, Duloxetine STADA Arzneimittel AG and Duloxetine STADA AG.

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

There are no studies required for Duloxetine STADA, Duloxetine STADA Arzneimittel AG and Duloxetine STADA AG.