Summary of the Swiss risk management plan
for
Latuda®
Lurasidoni hydrochloridum

Document version :1.0 (30.08.2023)
Based on : core RMP version 9.1 (22.12.2022)
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The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them.
The RMP summary of Latuda® is a concise document and does not claim to be exhaustive.
As the RMP is an international document, the summary might differ from the “Arzneimittelinformation / Information sur le médicament” approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.
Please note that the reference document which is valid and relevant for the effective and safe use of Latuda® in Switzerland is the “Arzneimittelinformation/ Information sur le médicament” (see www.swissmedic.ch) approved and authorized by Swissmedic. Medius AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Latuda®.

Summary of risk management plan for Latuda® (lurasidone)

This is a summary of the risk management plan (RMP) for Latuda. The RMP details important risks of Latuda, how these risks can be minimised, and how more information will be obtained about Latuda's risks and uncertainties (missing information).
Latuda's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Latuda should be used.
Important new concerns or changes to the current ones will be included in updates of Latuda's RMP.

I. The medicine and what it is used for

Latuda is authorised for the treatment of patients with schizophrenia, and as monotherapy or as adjunctive therapy with lithium or valproate for acute treatment of depressive episodes associated with bipolar disorder type I in adults (see SmPC for the full indication). It contains lurasidone as the active substance and it is given by oral route of administration.

II. Risk associated with the medicine and activities to minimize or further characterize the risks

Important risks of Latuda, together with measures to minimise such risks and the proposed studies for learning more about Latuda's risks, are outlined below.
Measures to minimise the risks identified for medicinal products are:

- 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 Latuda is not yet available, it is listed under “missing information” below.

II.A List of important risks and missing information

Important risks of Latuda are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered.
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 Latuda. 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	None
Important potential risks	None
Missing information	Pregnant or lactating women

II.B Summary of important risks

Missing information: Pregnant or lactating women	
Risk minimisation measures	Routine risk minimization measures: • SmPC section Pregnancy, lactation. • PL section *Can Latuda be taken during pregnancy or when breast-feedin*g? Additional risk minimization measures: None

II.C Post-authorization 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 Latuda.

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

There are no studies required for Latuda.