

Summary of risk management plan for Levomepromazine Morningside 25 mg & 100 mg Tablets (herein referred to as Levomepromazine Tablets):

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

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

I. The medicine and what it is used for

Levomepromazine Tablets are authorised :

- For the attenuation of psychomotor restlessness and excitability in psychotic disorders,
- for acute states of agitation during manic episodes,
- and as part of a combined therapy in the treatment of severe and/or chronic pain.

It contains levomepromazine maleate as the active substance and 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 Levomepromazine Tablets, together with measures to minimise such risks and the proposed studies for learning more about Levomepromazine Tablets' 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 PL and SmPC addressed to patients and health care 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

Important risks of Levomepromazine Tablets 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 Levomepromazine Tablets. 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	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

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 Levomepromazine Tablets.

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

There are no studies required for Levomepromazine Tablets.