

Summary of risk management plan for Froidir (clozapine) Orion Corporation

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

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

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

I. The medicine and what it is used for

Froidir is authorised for treatment of treatment-resistant schizophrenia, and for treatment of psychosis during the course of Parkinson's disease (see SmPC for the full indication). It contains clozapine 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 Froidir, together with measures to minimise such risks and the proposed studies for learning more about Froidir'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 the case of Froidir, these measures are supplemented with additional risk minimisation measures mentioned under relevant important risks, below.

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 Froidir 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 Froidir. 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	<ul style="list-style-type: none"> • Agranulocytosis • Cardiovascular disorders including (orthostatic hypotension, myocarditis and cardiomyopathy, pericarditis/pericardial effusion, QT prolongation, myocardial infarction, thromboembolism, circulatory collapse)
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.

Important identified risk: Agranulocytosis	
Risk minimisation measures	<p>Routine risk minimisation measures:</p> <p>Boxed warnings in SmPC sections 1 and 4.4.</p> <p>Information in SmPC sections 1, 4.2, 4.3, 4.4, 4.8 and 5.1, and PL sections 2 and 4.</p> <p>Additional risk minimisation measures:</p> <p>Educational material for healthcare professionals and Guide for patients</p>

Important identified risk: Myocarditis and cardiomyopathy	
Risk minimisation measures	<p>Routine risk minimisation measures:</p> <p>Boxed warning in SmPC section 1.</p> <p>Information in SmPC sections 4.3, 4.4 and 4.8, and PL sections 2 and 4.</p> <p>Additional risk minimisation measures:</p> <p>Educational material for healthcare professionals and Guide for patients</p>

II.C Post-authorisation development plan

There are no studies required for Froidir.