Summary of the Risk Management Plan (RMP) for Sarclisa®

Sarclisa® (isatuximab)
Marketing Autorisation Holder: sanofi-aventis (suisse) sa
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Disclaimer:
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 minimize them.

The RMP summary of Sarclisa® 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 medicament” 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 Sarclisa® in Switzerland is the “Arzneimittelinformation/ Information sur le medicament” (see www.swissmedicinfo.ch) approved and authorized by Swissmedic. Sanofi-aventis (suisse) sa is fully responsible for the accuracy and correctness of the content of this published summary RMP of Sarclisa®.
Summary of risk management plan for SARCLISA (Isatuximab)

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

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

This summary of the RMP for SARCLISA should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

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

VI.1. THE MEDICINE AND WHAT IT IS USED FOR

SARCLISA is an anti-cancer medicine that contains the active substance isatuximab. It belongs to a group of medicines called “monoclonal antibodies”. SARCLISA is used to treat “multiple myeloma”. This is a type of cancer of your bone marrow.

SARCLISA is used together with two other medicines called pomalidomide and dexamethasone. This treatment is for adult patients with relapsed and refractory multiple myeloma who have received at least two treatments for multiple myeloma before and have demonstrated disease progression on the last therapy.

Further information about the evaluation of SARCLISA’s benefits can be found in SARCLISA’s EPAR, including in its plain-language summary, available on the European Medicines Agency (EMA) website, under the medicine’s webpage:

Link to the EPAR summary landing page to be added by EMA

VI.2. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMIZE OR FURTHER CHARACTERIZE THE RISKS

Important risks of SARCLISA, together with measures to minimize such risks and the proposed studies for learning more about SARCLISA’s risks, are outlined in the next sections.

Measures to minimize 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 authorized 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 (eg, with or without prescription) can help to minimize its risks.

Together, these measures constitute routine risk minimisation measures.

In the case of SARCLISA, these measures are supplemented with additional risk minimisation measures mentioned under relevant important risks, outlined in the next sections.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including periodic safety update report (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 SARCLISA is not yet available, it is listed under ‘missing information’ outlined in the next section.

VI.2.1. List of important risks and missing information

Important risks of SARCLISA are risks that need special risk management activities to further investigate or minimize 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 SARCLISA. 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 (eg, on the long-term use of the medicine).

<table>
<thead>
<tr>
<th>Important identified risk</th>
<th>Interference with indirect antiglobulin test (indirect Coombs test) and possible resulting adverse clinical consequences for the patient (bleeding due to transfusion delay, transfusion haemolysis)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Important potential risk</td>
<td>None</td>
</tr>
<tr>
<td>Missing information</td>
<td>None</td>
</tr>
</tbody>
</table>
VI.2.2. Summary of important risks

Table 2 – Important identified risk: Interference with indirect antiglobulin test (indirect Coombs test) and possible resulting adverse clinical consequences for the patient (bleeding due to transfusion delay, transfusion haemolysis) with corresponding risk minimization activities and additional pharmacovigilance activities

<table>
<thead>
<tr>
<th>Interference with indirect antiglobulin test (indirect Coombs test) and possible resulting adverse clinical consequences for the patient (bleeding due to transfusion delay, transfusion haemolysis)</th>
<th>Evidence for linking the risk to the medicine</th>
<th>Risk factors and risk groups</th>
<th>Risk minimization measures</th>
<th>Additional pharmacovigilance activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class effect: isatuximab binds to RBCs and may interfere with routine blood bank compatibility tests. Interference for blood typing has occurred during clinical trials.</td>
<td>Patients with MM may require blood transfusions (as it has occurred in 30% of the patients in study EFC14335), because of morbidity from MM and its treatment.</td>
<td>Routine risk minimization measures: SmPC Sections 4.4 and 4.5. Legal status: Available only on prescription. Isatuximab should be administered by a HCP, in an environment where resuscitation facilities are available (SmPC section 4.2). Additional risk minimization measures: Healthcare Professionals and blood banks educational material (including brochure and PAC).</td>
<td>Non-interventional PASS survey to measure the effectiveness of the isatuximab educational materials, to minimize the risk of interference with indirect antiglobulin test and possible resulting adverse clinical consequences for the patient (bleeding due to transfusion delay, transfusion haemolysis).</td>
<td></td>
</tr>
</tbody>
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VI.2.3. Post-authorization development plan

VI.2.3.1. Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of SARCLISA.VI.2.3.2. Other studies in post-authorization development plan

Table 3 - Other studies in post-authorization development plan

Non-interventional PASS survey to measure the effectiveness of the isatuximab educational materials, to minimize the risk of interference with indirect antiglobulin test and possible resulting adverse clinical consequences for the patient (bleeding due to transfusion delay, transfusion haemolysis).

Purpose of the study: To assess HCP’s/Blood banks awareness, knowledge and behaviour with respect to the minimization of the risk of interference for blood typing with isatuximab.