# Summary of the risk management plan

## Summary of risk management plan for Pedmarqsi <sodium thiosulfate>

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

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

This summary of the RMP for Pedmarqsi 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 Pedmarqsi's RMP.

# I. The medicine and what it is used for

Pedmarqsi is authorised for the prevention of ototoxicity induced by cisplatin chemotherapy in patients 1 month to < 18 years of age with localized, non-metastatic, solid tumours (see SmPC for the full indication). It contains sodium thiosulfate as the active substance and it is given by intravenous 15-minute infusion.

Further information about the evaluation of Pedmarqsi's benefits can be found in Pedmarqsi's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage https://www.ema.europa.eu/en/medicines/human/EPAR/pedmarqsi.

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

Important risks of Pedmarqsi, together with measures to minimise such risks and the proposed studies for learning more about Pedmarqsi'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 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 Pedmarqsi is not yet available, it is listed under 'missing information' below.

## *II.A List of important risks and missing information*

Important risks of Pedmarqsi 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 Pedmarqsi. 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).

| **Summary of safety concerns** | |
|---|---|
| **Important identified risks** | None |
| **Important potential risks** | • Anaphylactic reactions<br>• Medication errors |
| **Missing information** | • Long-term safety |

## *II.B Summary of important risks*

| **Important potential risk:** Anaphylactic reactions | |
|---|---|
| Evidence for linking the risk to the medicine | Anaphylactic reactions have not been observed with Pedmarqsi thus far, however, this potential event, including severe symptoms, cannot be ruled out. |
| Risk factors and risk groups | Patients with known hypersensitivities |
| Risk minimisation measures | Routine risk minimisation measures: Please see SmPC sections 4.4 Special warnings and precautions for use, and 4.8 Undesirable effects; PL sections 2.2 Recommended Premedications, 2.3 Dosage Modifications for Adverse Reactions, 4 Contraindications, and 5 Warnings and Precautions<br><br>Routine risk minimisation activities recommending specific clinical measures to address the risk: None proposed<br><br>Other routine risk minimisation measures beyond the Product Information: Legal status<br><br>Additional risk minimisation measures: None proposed |
| Additional pharmacovigilance activities | None proposed |

| **Important potential risk:** Medication errors | |
|---|---|
| Evidence for linking the risk to the medicine | Medication errors have not been observed with Pedmarqsi thus far, however, this potential event, including decrease of cisplatin efficacy, cannot be ruled out. |
| Risk factors and risk groups | Complex dosing schedule |
| Risk minimisation measures | Routine risk minimisation measures: Please see SmPC sections 4.2 Posology and method of administration, PL section 1 Indication and Usage and 2 Dosage and Administration<br><br>Routine risk minimisation activities recommending specific clinical measures to address the risk: None proposed<br><br>Other routine risk minimisation measures beyond the Product Information: Legal status<br><br>Additional risk minimisation measures: None proposed |
| Additional pharmacovigilance activities | None proposed |

| **Missing information:** Long-term safety | |
|---|---|
| Evidence for linking the risk to the medicine | Only 118 children were treated with STS in Fennec's clinical trials, therefore, long-term safety data are limited |
| Risk minimisation measures | Routine risk minimisation measures: None proposed<br><br>Routine risk minimisation activities recommending specific clinical measures to address the risk: None proposed<br><br>Other routine risk minimisation measures beyond the Product Information: Legal status<br><br>Additional risk minimisation measures: None proposed |
| Additional pharmacovigilance activities | None proposed |

## *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 a specific obligation of Pedmarqsi.

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

There are no other studies in the post-authorisation plan of Pedmarqsi.