Part VI: Summary of the risk management plan

Summary of risk management plan for Selesyn (sodium selenite pentahydrate)

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

Selesyn's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Selesyn should be used. This summary of the RMP for Selesyn 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 EPAR.

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

I. The medicine and what it is used for

Selesyn is authorised for the treatment of clinically proven selenium deficiency (see SmPC for the full indication). It contains sodium selenite pentahydrate as the active substance and it is given intravenous, intramuscular (solution for injection/infusion) and orally (oral solution and tablets).

Selenium is an essential trace element. Selenium deficiency may be caused by an inadequate nutritional supply or be associated with a wide range of diseases. There are no representative epidemiological studies on the incidence or extent of selenium deficiency, therefore it has to be proven in every single case.

Restoration of body selenium reservoirs will lead to full activity of selenoenzymes. Selenoenzymes are essential for a number of important physiological activities, e.g. thyroid hormone synthesis, adequate function of the immune system, down-regulation of non-physiological inflammation reactions, repair of genetic material, adequate function of anti-oxidative defence mechanisms.

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

Important risks of Selesyn, together with measures to minimise such 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, such as warnings, precautions, and advice on correct use;
- 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 public (e.g. with or without prescription) can help to minimises its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse events is collected continuously and regularly analysed, including PSUR assessment, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

1.1. List of important risks and missing information

Important risks of Selesyn can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Selesyn. Potential risks are concerns for which an association with the use of this medicine is possible based on some preliminary data, but this association has not been fully proven and needs further evaluation.

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

1.2. Summary of important risks

Not applicable.

1.3. Summary of missing information

Not applicable.

1.4. Post-authorisation development plan

Not applicable.

1.4.1. Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Selesyn.

1.4.2. Other studies in post-authorisation development plan

There are no studies required for Selesyn.