

VI.2 Elements for a Public Summary

VI.2.1 *Overview of disease epidemiology*

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.

VI.2.2 *Summary of treatment benefits*

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.

VI.2.3 *Unknowns relating to treatment benefits*

Not applicable.

VI.2.4 *Summary of safety concerns*

Important identified risks

None

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Selenium intoxication (selenosis)	Selenium supplementation is only initiated after detecting a pronounced selenium deficiency. In the special form of selenite, potential intoxications are avoided by easy excretion of potential excess concentrations. A garlic-like breath can serve as an early warning symptom.

Missing information

None

VI.2.5 *Summary of risk minimisation measures by safety concern*

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

This medicine has no additional risk minimisation measures.

VI.2.6 *Planned post authorisation development plan*

Not applicable.

VI.2.7 *Summary of changes to the Risk Management Plan over time*

Not applicable.