

Summary of risk management plan for Natriumklorid Abboxia 500 mg film-coated tablets (sodium chloride)

This is a summary of the risk management plan (RMP) for Natriumklorid Abboxia 500 mg film-coated tablets.

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

I. The medicine and what it is used for

Natriumklorid Abboxia is authorised for symptomatic chronic euvolemic hyponatremia when insufficient efficacy of fluid restriction and/or diuretic therapy (e.g. Syndrome of Inappropriate Antidiuretic hormone secretion, SIADH) and for hypovolemic hyponatraemia (e.g. ileostomy/jujenostomy). It contains sodium chloride as the active substance and is given by oral route.

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

There are no important risks for Natriumklorid Abboxia.

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

There are no important risks for Natriumklorid Abboxia.

II.B Summary of important risks

There are no important risks for Natriumklorid Abboxia.

II.C Post-authorisation development plan

There are no studies required for Natriumklorid Abboxia.