

Summary of risk management plan for Tetana (tetanus toxoid)

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

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

I. The medicine and what it is used for

Tetana is authorised for active immunisation of children, adolescents and adults against tetanus (see SmPC for the full indication). It contains tetanus toxoid as the active substance and is presented as a suspension for injection.

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

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

ILA List of important risks and missing information

Important risks of Tetana 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 Tetana. 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).

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

rr.B Summary of important risks

The safety concerns for Tetana are well described in the product information, they do not contain additional risk minimisation measures, additional pharmacovigilance activities as well as follow-ups. Moreover, the routine pharmacovigilance activities are completely sufficient to identify actual or potential risks.

rr.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 specific obligation of Tetana.

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

There are no studies required for Tetana.