

Summary of risk management plan for VAXNEUVANCE™ (Pneumococcal polysaccharide conjugate vaccine (15 valent, adsorbed))

This is a summary of the risk management plan (RMP) for VAXNEUVANCE™. The RMP details important risks of VAXNEUVANCE™, and how more information will be obtained about pneumococcal polysaccharide conjugate vaccine (15 valent, adsorbed)'s risks and uncertainties (missing information).

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

This summary of the RMP for VAXNEUVANCE™ 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 VAXNEUVANCE's™ RMP.

I. The Medicine and What It Is Used For

VAXNEUVANCE™ is authorised for active immunisation for the prevention of invasive disease, pneumonia and acute otitis media caused by *Streptococcus pneumoniae* in infants, children and adolescents from 6 weeks to less than 18 years of age. VAXNEUVANCE™ is authorised for active immunization for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in individual 18 years of age and older (see SmPC for the full indication). It contains pneumococcal polysaccharide conjugate vaccine (15 valent, adsorbed) as the active substance and it is given by intramuscular injection.

Further information about the evaluation of VAXNEUVANCE's™ benefits can be found in VAXNEUVANCE's™ EPAR, including in its plain-language summary, available under the medicine's webpage link to product's EPAR summary landing page on the EMA webpage.

II. Risks Associated With the Medicine and Activities to Minimise or Further Characterise the Risks

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

II.A List of Important Risks and Missing Information

Important risks of VAXNEUVANCE™ 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 VAXNEUVANCE™. 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).

Table II.A.1: List of Important Risks and Missing Information

List of Important Risks and Missing Information	
Important identified risks	None
Important potential risks	None
Missing information	None*
* The missing information included in prior versions of the RMP has been removed based on the review of accumulating clinical data and the guidance in GVP module 5 (Rev 2), as per routine updates of the RMP during the life cycle of the product.	

II.B Summary of Important Risks

There are no important identified or potential risks for VAXNEUVANCE™. “Use in adult HSCT recipients” previously classified as missing information is removed from the list of safety concerns.

II.C Post-Authorisation Development Plan

II.C.1 Studies Which are Conditions of the Marketing Authorisation

Study V114-032: A Study of V114 and Acute Otitis Media in Children

Purpose of the study: To evaluate the efficacy of V114 in preventing vaccine-type (VT) pneumococcal AOM in children.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for VAXNEUVANCE.