

**Table 77. List of Important Risks and Missing Information**

Important identified risks	Myocarditis and Pericarditis
Important potential risks	Vaccine-associated enhanced disease (VAED) including Vaccine-associated enhanced respiratory disease (VAERD)
Missing information	Use in pregnancy and while breast feeding Use in immunocompromised patients Use in frail patients with co-morbidities (e.g., chronic obstructive pulmonary disease [COPD], diabetes, chronic neurological disease, cardiovascular disorders) Use in patients with autoimmune or inflammatory disorders Interaction with other vaccines Long term safety data

### II.B Summary of Important Risks

The safety information in the Product Information is aligned to the reference.

**Table 78. Important Identified Risk: Myocarditis and Pericarditis**

Evidence for linking the risk to the medicine	Events of Myocarditis and Pericarditis have been reported.
Risk factors and risk groups	Post-authorization reports have been reported more frequently in adolescent and young adult male patients following the second dose of vaccine; however, reports have been received for adult males and females of broader age range and following the first vaccination also.
Risk minimisation measures	Routine risk minimisation measures: SmPC sections 4.4. and 4.8.  Additional risk minimisation measures: DHCP letter and communication plan
Additional pharmacovigilance activities	C4591009 C4591011 C4591012 C4591021 (former ACCESS/VAC4EU) C4591038 (former C4591021 sub-study) C4591036 (former Pediatric Heart Network study) See Section II.C this summary for an overview of the post-authorisation development plan.