

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	<u>Routine risk minimisation measures:</u> SmPC sections 4.4. and 4.8. <u>Additional risk minimisation measures:</u> 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.