Part VI Summary of the risk management plan

VI.1 Elements for summary tables in the EPAR

VI.1.1 Summary table of Safety concerns

Summary of safety concerns	
Important identified risks	• Priapism • Hypotension/increased hypotensive effect
Important potential risks	• Nonarteritic Anterior Ischemic Optic Neuropathy (NAION) • Sudden hearing loss
Missing information	• Characterisation of adverse events in elderly patients (≥65 years)

VI.1.2 Table of on-going and planned additional PhV studies/activities in the Pharmacovigilance Plan

Not applicable.

VI.1.3 Summary of Post authorisation efficacy development plan

No study planned.

VI.1.4 Summary table of risk minimisation measures

Safety concern	**Routine risk minimisation measures**	**Additional risk minimisation measures**
Important identified risks		
Priapism	Included in SPC section(s) • 4.4 Special warnings and precautions for use • 4.8 Undesirable effects	NA
Hypotension/increased hypotensive effect	Included in SPC section(s) • 4.3 Contraindications • 4.4 Special warnings and precautions for use • 4.5 Interaction with other medicinal products and other forms of interaction	NA

	• 4.8 Undesirable effects	
Important potential risks		
Nonarteritic Anterior Ischemic Optic Neuropathy (NAION)	Included in SPC section(s) • 4.3 Contraindications • 4.4 Special warnings and precautions for use • 4.8 Undesirable effects	NA
Sudden hearing loss	Included in SPC section(s) • 4.8 Undesirable effects	NA
Missing information		
Characterisation of adverse events in elderly patients (≥65 years)	Included in SPC section(s) • 4.8 Undesirable effects	NA

Tadalafil was first approved in 2002. A well-established safety profile based on more than 10 years of post-authorisation experience with the originator product exists.

STADA Arzneimittel AG has an adequate Pharmacovigilance System in place.

All potential and identified risks as well as interactions and missing information are sufficiently covered in the respective sections of the SPC. Therefore, no additional pharmacovigilance and risk minimisation activities are deemed necessary.