WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Streptomycin (as sulfate) 1g powder for injection*

International Nonproprietary Name(s) (INN):
streptomycin (as sulfate)

Abstract

Streptomycin (as sulfate) 1g powder for injection manufactured at NCPC New Preparation Branch Factory, Hebei, China was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 30 June 2017.

Streptomycin (as sulfate) 1g powder for injection is indicated in combination with other antituberculosis agents for the treatment of tuberculosis caused by streptomycin -sensitive strains of *Mycobacterium tuberculosis* when first-line drugs cannot be used because of resistance or intolerance. Streptomycin should only be used when other second-line injectable agents, aminoglycosides or capreomycin, cannot be used. Detailed information on the use of this product is described in the Summary of Product Characteristics (SmPC), which can be found in this WHOPAR.

The active pharmaceutical ingredient (API) of Streptomycin (as sulfate) 1g powder for injection is the antibacterial agent, streptomycin. The API is documented for the treatment of tuberculosis and other bacterial infections.

The most frequent adverse events observed during treatment with streptomycin were vestibular ototoxicity (nausea, vomiting, and vertigo), paraesthesia of face, rash, fever, urticarial, angioedema and eosinophilia.

The most serious safety concerns with streptomycin are cochlear ototoxicity (deafness), anaphylaxis, haemolytic anaemia and aplastic anaemia.

The efficacy and safety profile of Streptomycin (as sulfate) 1g powder for injection is well established based on extensive clinical experience in the treatment of bacterial infections.

On the basis of data submitted and public information on the use of Streptomycin (as sulfate) 1g powder for injection in tuberculosis, the team of assessors advised that Streptomycin (as sulfate) 1g powder for injection is of acceptable quality, efficacy and safety to allow inclusion of Streptomycin (as sulfate) 1g powder for injection in the list of prequalified medicinal products.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

Summary of Prequalification Status for Streptomycin (as sulfate) 1g powder for injection

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	30 June 2017	listed				
Dossier Evaluation (Quality assurance)						
Quality	15 June 2017	MR				
Bioequivalence	15 June 2017	MR				
Inspection Status						
GMP(re-)inspection						
API	21 Oct 2016	MR				
FPP	05 Feb 2016	MR				
GCP (re-)inspection	NA	NA				

MR: meets requirements
NA: not applicable, not available