WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB327 trade name] [1]

Kanamycin (as sulfate) 500mg/2ml Solution for Injection [1]

Abstract

[TB327 trade name], manufactured at Livzon (Group) Pharmaceutical Factory, Guangdong, People's Republic of China, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 06 February 2019.

[TB327 trade name], is indicated in combination with other antituberculosis agents for the treatment of tuberculosis caused by kanamycin-sensitive strains of *Mycobacterium tuberculosis*. Kanamycin is only indicated as a second-line antimycobacterial drug when first-line drugs cannot be used because of resistance or intolerance.

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 [TB327 trade name], is the antimycobacterial agent kanamycin. The API is well established and documented for the treatment of tuberculosis.

The most serious safety concerns with kanamycin are nephrotoxicity and ototoxicity.

Other adverse reactions reported are anaphylaxis, hypersensitivity reactions, rash, anaemia, blood dyscrasias, purpura, headache, nausea, vomiting, diarrhoea, stomatitis, antibiotic–associated colitis, electrolyte disturbances, and effects on liver function. The "malabsorption syndrome" characterized by an increase in faecal fat, decrease in serum carotene, and fall in xylose absorption, has occurred with prolonged therapy.

Local reactions have included pain at the injection site after intramuscular injection.

The efficacy and safety profile of kanamycin is well established based on extensive clinical experience in the treatment of tuberculosis.

On the basis of data submitted and public information on the use of kanamycin in antituberculosis therapy, the team of assessors advised that [TB327 trade name], is of acceptable quality, efficacy and safety to allow inclusion of [TB327 trade name], in the list of prequalified medicinal products.

[1] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

Summary of Prequalification Status for [TB327 trade name].

Initial acceptance	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	06 February 2019	listed
Quality	21 January 2019	MR
Bioequivalence	31 January 2019	MR
Safety, Efficacy	NA	NA
GMP (re-)inspection		
API	16 March 2017	MR
FPP	02 November 2017	MR
GCP/GLP (re-)inspection	NA	NA

MR: meets requirements
NA: not applicable, not available