WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Para-aminosalicylate sodium delayed-release granules 60% w/w [*]

International Nonproprietary Name (INN):
Para-aminosalicylate sodium

Abstract

Para-aminosalicylate sodium delayed-release granules 60% w/w manufactured at Macleods Pharmaceuticals Ltd, Kachigan, Daman (U.T.), India was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 14 December 2009.

Para-aminosalicylate sodium delayed-release granules 60% w/w is indicated for the treatment of tuberculosis. Detailed information on the use of this product is described in the Summary of Product Characteristics (SPC), which can be found in this WHOPAR.

The active pharmaceutical ingredient (API) of Para-aminosalicylate sodium delayed-release granules 60% w/w is the antimycobacterial agent para-aminosalicylate sodium. The API is well-established and documented for the treatment of tuberculosis.

The most frequent adverse events observed during treatment with para-aminosalicylate sodium were nausea, vomiting and abdominal pain.

The most important adverse effect of para-aminosalicylate sodium are optic neuritis, encephalopathy, exfoliative dermatitis, agranulocytosis, and eosinophilic pneumonia.

The efficacy and safety profile of Para-aminosalicylate sodium 60% granules 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 para-aminosalicylate sodium in tuberculosis, the team of assessors advised that Para-aminosalicylate sodium 60% granules is of acceptable quality, efficacy and safety to allow inclusion of Para-aminosalicylate sodium 60% granules in the list of prequalified medicinal products.

[*] Trade names are not prequalified by WHO. This is under local DRA responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

Summary of Prequalification Status for Para-aminosalicylate sodium delayed-release granules 60%w/w:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list	14 Dec 2009	listed				
Dossier Evaluation						
Quality	8 Dec 2009	MR				
Bioequivalence	8 Sept 2009	MR				
Safety, Efficacy	NA	NA				
Inspection Status						
GMP(re-)inspection						
API	18 June 2009	MR				
FPP	20 June 2007	MR				
GCP (re-)inspection	NA	NA				
Batch Analysis	NA	NA				

MR: meets Requirements
NA: not applicable, not available