WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Ceftriaxone (as sodium) 500mg Powder for Injection *

International Nonproprietary Name (INN)
Ceftriaxone (as sodium)

Abstract

Ceftriaxone (as sodium) 500mg Powder for Injection manufactured at Egyptian International Pharmaceutical Industries Company, Egypt was included in the WHO list of prequalified medicinal products for the treatment of bacterial infections in Human Immunodeficiency Virus (HIV)/AIDS patients on 16 May 2014.

Ceftriaxone (as sodium) 500mg Powder for Injection is indicated for the treatment of bacterial infections. 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 Ceftriaxone (as sodium) 500mg Powder for Injection is the antibacterial agent ceftriaxone. The API is well-established and documented for the treatment of bacterial infections.

The most frequent adverse events observed during treatment with ceftriaxone were eosinophilia, leucopenia, thrombocytopenia, diarrhoea, rash, and hepatic enzymes increased.

The most serious safety concerns with ceftriaxone are renal and hepatic dysfunction.

The efficacy and safety profile of ceftriaxone 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 ceftriaxone in bacterial infections, the team of assessors advised that Ceftriaxone (as sodium) 500mg Powder for Injection is of acceptable quality, efficacy and safety to allow inclusion of Ceftriaxone (as sodium) 500mg Powder for Injection in the list of prequalified medicinal products.

1 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 Ceftriaxone (as sodium) 500mg Powder for Injection:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	16 May 2014	listed				
Dossier Evaluation (Quality assurance)						
Quality	07 April 2014	MR				
Bioequivalence	28 April 2014	MR				
Safety, Efficacy	NA	NA				
Inspection Status						
GMP(re-)inspection						
API	NA	NA				
FPP	04 March 2013	MR				
GCP/GLP (re-)inspection	NA	NA				

MR: meets requirements
NA: not applicable, not available