WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Oseltamivir (as phosphate) Capsules 75 mg*

International Nonproprietary Name (INN):
Oseltamivir

Abstract

Oseltamivir (as phosphate) Capsules 75 mg, manufactured at Mylan Laboratories Limited, Waluj Industrial Area, Aurangabad, India was accepted for the WHO list of prequalified products for the treatment and prevention of influenza on 13 June 2014.

Oseltamivir (as phosphate) Capsules 75 mg is indicated for the treatment and prevention of influenza. 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 Oseltamivir (as phosphate) Capsules 75 mg is oseltamivir (as phosphate), a prodrug of the active metabolite oseltamivir carboxylate. Oseltamivir carboxylate selectively inhibits influenza virus neuraminidase enzymes, which are present on the virus surface. Viral neuraminidase is important for viral entry into uninfected cells and for the release of recently formed virus particles from infected cells. Inhibiting this enzyme reduces spread of the enzyme in the body.

Oseltamivir has been investigated for the treatment of influenza in adults and in children. It has also been studied for post-exposure prophylaxis in in seasonal prophylaxis at the community level.

The most frequent adverse effects of capreomycin include nausea, vomiting, diarrhoea, stomachache, and headache. Vomiting was reported to occur very frequently in children.

On the basis of data submitted and public information on the use of oseltamivir in influenza treatment and prophylaxis, the team of assessors accepted Oseltamivir (as phosphate) Capsules 75 mg for 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 Oseltamivir (as phosphate) Capsules 75 mg:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list (i.e. date of listing)	13 Jun 2014	listed				
Dossier Evaluation (Quality assurance)						
Quality	28 May 2014	MR				
Bioequivalence	3 Jun 2014	MR				
Safety, Efficacy	NA	NA				
Inspection Status						
GMP(re-)inspection[†]						
API		MR				
FPP	11 May 2103	MR				
GLP (re-)inspection[‡]		MR				
GCP (re-)inspection		MR				

MR: Meets Requirements
NA: Not applicable, not available

[†] Not inspected for GMP. Previous site inspections by WHO showed acceptable outcome
[‡] Not inspected for GLP/GCP. Previous site inspections by WHO showed acceptable outcome