WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Oseltamivir Capsules 75 mg*

International Nonproprietary Name (INN*):*
Oseltamivir

Abstract

Oseltamivir Capsules 75 mg, manufactured at Cipla Ltd., 403 722 GOA, India was accepted for the WHO list of prequalified products for the treatment and prophylaxis of influenza infection on 13 May 2009.

Oseltamivir Capsules 75 mg is indicated for the treatment and prophylaxis of influenza virus A and influenza virus B infection. 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 Oseltamivir Capsules 75 mg is oseltamivir (as phosphate), a pro-drug of the active metabolite oseltamivir carboxylate. The latter is a selective inhibitor of influenza virus neuraminidase enzymes, which are glycoproteins found on the virion surface. Viral neuraminidase enzyme activity is important both for viral entry into uninfected cells and for the release of recently formed virus particles from infected cells. By inhibition of this enzyme further spread of infectious virus in the body is reduced.

Oseltamivir has been investigated in the treatment of influenza in the adults and in children. Furthermore, studies have been conducted in postexposure prophylaxis and in seasonal prophylaxis at the community level.

The most frequent adverse events observed with oseltamivir were nausea, vomiting, diarrhoea, stomach ache and headache. Vomiting was reported very frequently in children.

On the basis of data submitted and publicly available information on the use of oseltamivir in influenza prophylaxis and treatment, the team of assessors accepted Oseltamivir Capsules 75 mg for 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 Oseltamivir Capsules 75 mg:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list	13 May 2009	listed				
Dossier Evaluation						
Quality	07 May 2009	MR				
Bioequivalence	23 July 2008	MR				
Safety, Efficacy	NA	NA				
Inspection Status						
GMP(re-)inspection						
API	14 Oct 2006	MR				
FPP	17 Mar 2008	MR				
GCP (re-)inspection	24 Feb 2009	MR				
Batch Analysis	NA	NA				

MR: meets requirements
NA: not applicable, not available