WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Oseltamivir (as phosphate) 75 mg Capsules*

International Nonproprietary Names (INN*):*
Oseltamivir

Abstract

Oseltamivir (as phosphate) 75 mg Capsules, manufactured at Strides Arcolab Ltd, Bangalore-562 106, India was included in the WHO list of prequalified medicinal products for the treatment and prophylaxis of influenza infection on 25 October 2010.

Oseltamivir (as phosphate) 75 mg Capsules is indicated for the treatment and prophylaxis of both 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 (as phosphate) 75 mg Capsules 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.

The most serious adverse events were anaphylactic reactions, hepatitis, gastrointestinal bleeding, neuropsychiatric events, such as hallucination, self-injury or convulsion and serious skin reactions such as Stevens-Johnson syndrome.

On the basis of data submitted and public information on the use of oseltamivir in influenza prophylaxis and treatment, the team of assessors advised that Oseltamivir (as phosphate) 75 mg Capsules is of acceptable quality, efficacy and safety to allow inclusion of Oseltamivir (as phosphate) 75 mg Capsules in 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) 75 mg Capsules:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list	25 Oct 2010	listed				
Dossier Evaluation						
Quality	06 Oct 2010	MR				
Bioequivalence	10 Oct 2010	MR				
Safety, Efficacy	NA	NA				
Inspection Status						
GMP(re-)inspection						
API	23 Oct 2009	MR				
FPP	21 Nov 2009	MR				
GCP (re-)inspection	10 Oct 2010	MR				
Batch Analysis	NA	NA				

MR: meets requirements
NA: not applicable, not available