WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Oseltamivir (as phosphate) 30 mg Capsules*

Abstract

Oseltamivir (as phosphate) 30 mg Capsules, manufactured at Macleods Pharmaceuticals Ltd, Himachal Pradesh, India was accepted for the WHO list of prequalified products for the treatment and prevention of influenza on 21 December 2016.

Oseltamivir (as phosphate) 30 mg Capsules 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) 30 mg Capsules 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 virus 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 seasonal prophylaxis at the community level.

The most frequent adverse events of oseltamivir include nausea, vomiting, diarrhoea, stomach ache, 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) 30 mg Capsules for the list of prequalified medicinal products.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

Summary of Prequalification Status for Oseltamivir (as phosphate) 30 mg Capsules:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	21 Dec 2016	listed				
Dossier Evaluation (Quality assurance)						
Quality	19 Dec 2016	MR				
Bioequivalence	16 Dec 2016	MR				
Safety, Efficacy	NA	NA				
Inspection Status						
GMP(re-)inspection						
API	12 Aug 2016	MR				
FPP	17 July 2014	MR				
GLP (re-)inspection	24 March 2016	MR				

MR: meets requirements
NA: not applicable, not available