WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Tamiflu® 75 mg hard capsules [1]

International Nonproprietary Name (INN):
Oseltamivir (as phosphate)

Abstract

Tamiflu® 75 mg hard capsules, manufactured at Cenexi SAS, France, Catalent Germany Schorndorf GmbH, Germany, Patheon Manufacturing Services LLC,USA, Delpharm Milano S.r.l,Italy and Roche Pharma AG, Germany was submitted to be considered for prequalification in 2009 when the product was licensed / registered in the European Union and subsequently accepted for the WHO list of prequalified products for the treatment and prophylaxis of influenza on 21 Sept 2009.

The "Procedure for prequalification of pharmaceutical products[2]" defines specific evaluation mechanisms for products approved by regulatory authorities, which apply similar stringent standards for quality, safety and efficacy as those required by WHO.

The prequalification of this product by the WHO Prequalification of Medicines Programme (PQP) is based on the approval by a stringent regulatory authority (SRA), namely the "European Medicines Agency" (EMA http://www.ema.europa.eu/ema/) in line with the "Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities"[3].

Hence, no assessment of the data underlying this approval has been undertaken within the WHO Prequalification Programme. However, according to the SRA guideline WHO may request additional data when considered necessary for the safe use of the product in regions relevant for prequalified products and such information may be included in the WHOPAR as a separate piece of information. In order to safeguard product quality throughout its entire intended shelf-life, stability studies under the conditions defined for Climatic Zones IVb have been requested from the Applicant.
Based on the submitted stability data WHO PQTm considers the following storage condition appropriate for the product when distributed in regions with zone III, IVa and IVb climatic conditions, based on available stability information:

"Do not store above 30°C.
The shelf-life at this storage condition is 48 months."

This WHOPAR refers to the information available at the approving stringent regulatory authority in terms of the assessment of the quality, efficacy and safety as well as steps taken after the prequalification (http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000402/human_med_001075.jsp&mid=WC0b01ac058001d124). (Web link accessed May 18, 2019)

[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.
[2] http://www.who.int/medicines/areas/quality_safety/quality_assurance/TRS961_Annex10.pdf
[3] http://apps.who.int/prequal/info_general/documents/TRS986/TRS986_ANNEX-5_SRA-Guide.pdf
https://extranet.who.int/prequal/sites/default/files/documents/75%20SRA%20clarification_February2017_0.pdf

WHOPAR part		**Reference** [4]
Part 1	Summary for the Public	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Summary_for_the_public/human/000402/WC500033101.pdf
Part 3	Package Leaflets	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000402/WC500033106.pdf
Part 4	Summaries Product Characteristics	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000402/WC500033106.pdf
Part 5	Labelling	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000402/WC500033106.pdf
Part 6	Discussion	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Scientific_Discussion/human/000402/WC500033103.pdf
Part 8	Steps taken following Authori-zation	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Procedural_steps_taken_and_scientific_information_after_authorisation/human/000402/WC500033105.pdf

Parts 2a, 2b and 7 of the WHOPAR for Tamiflu® 75 mg hard capsules are included here.

Tamiflu® 75 mg hard capsules contains oseltamivir (as phosphate).

Its WHO recommended use is for the treatment and prevention of influenza.

The most frequent adverse reactions observed during treatment with oseltamivir are nausea, vomiting, diarrhoea, stomach ache and headache.
The most serious adverse reactions of oseltamivir were anaphylactic reactions, hepatic disorders (fulminant hepatitis, hepatic function disorder and jaundice), angioneurotic oedema, Stevens-Johnson syndrome and toxic epidermal necrolysis, gastrointestinal bleeding and neuropsychiatric disorders.

The efficacy and safety profile of oseltamivir is well established based on the extensive clinical experience in the treatment of influenza.

[4] http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000402/human_med_001075.jsp&mid=WC0b01ac058001d124

Summary of Prequalification Status for Tamiflu® 75 mg hard capsules

	Initial Acceptance		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list	21 Sept 2009	listed	05 Feb 2018	listed
Dossier Evaluation	July 2009	MR	02 Feb 2018	requalified

MR: meets requirements

The table represents the status of relevant completed activities only.