WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

ERPIZON [1]

International Nonproprietary Name (INN):
Aciclovir 250mg Lyophilisate for Solution for Infusion

Abstract

ERPIZON, manufactured at DEMO SA was submitted to be considered for prequalification in 2013 when the product was licensed / registered in at least one of the ICH regions and subsequently accepted for the WHO list of prequalified products for the treatment of HIV/AIDS related conditions on 08 January 2014.

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 Greek Authority "National Organization for Medicines" (www.eof.gr) 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.

Based on the above, 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. Detailed information on the SRA-approved use of this product is described in the Summary of Product Characteristics (SmPC), which is a company authorized English translation of the Greek SmPC "and can be found in this WHOPAR. The most recent authorized Greek product information can be requested from the Greek Medicines Regulatory Agency (www.eof.gr).

Parts 2a, 2b, 3, 4, 5 and 7 of the WHOPAR for ERPIZON are included here.

ERPIZON contains aciclovir. Its WHO recommended use is for the treatment of herpes zoster, herpes simplex as well as the treatment of genital herpes in HIV infected patients.

The most frequent adverse events observed during treatment with aciclovir are phlebitis, nausea, vomiting, pruritus, rashes, renal and hepatic toxicity (e.g. elevations in blood urea and blood creatinine levels, reversible rises in liver enzymes).
The most serious adverse effects of aciclovir are hypersensitivity including anaphylaxis, dyspnoea angioedema and hepatitis.

[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://apps.who.int/prequal/info_general/documents/TRS961/TRS961_Annex10.pdf
[3] http://apps.who.int/prequal/info_general/documents/TRS986/TRS986_ANNEX-5_SRA-Guide.pdf

The efficacy and safety profile of aciclovir is well established based on the extensive clinical experience in the treatment of herpes simplex, herpes genitals and varicella zoster virus infections.

Summary of Prequalification Status for ERPIZON

	Initial Acceptance			
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	08 Jan 2014	listed		
Dossier Evaluation	02 Dec 2013	MR		

MR: meets requirements

The table represents the status of relevant completed activities only.