WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

ZOPHRALEN [1]

International Nonproprietary Name (INN):
Ondansetron (as hydrochloride dihydrate) 8mg/4ml Solution for Injection

Abstract

ZOPHRALEN, 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 21 Oct 2013.

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 "Guideline on Submission of Documentation for Prequalification of Multisource (generic) Finished Pharmaceutical Products (FPPs) approved by Stringent Regulatory Authorities (SRAs)"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 ZOPHRALEN are included here.

ZOPHRALEN contains ondansetron (as hydrochloride dihydrate). Its WHO recommended use is for the management of postoperative chemotherapy and radiotherapy induced nausea and vomiting in HIV/AIDS patients.

The most frequent adverse events observed during treatment with ondansetron (as hydrochloride dihydrate) were headache, sensation of warmth or flushing, and constipation.

The most serious adverse effects of ondansetron (as hydrochloride dihydrate) are hypersensitivity reactions including anaphylaxis, seizures, chest pain and cardiac arrhythmias

[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

(including QT interval prolongation, Torsade de pointes, ventricular fibrillations and cardiac arrest).

The efficacy and safety profile of ondansetron (as hydrochloride dihydrate) is well established based on extensive clinical experience in the treatment and the management of nausea and vomiting.

Summary of Prequalification Status for ZOPHRALEN

	Initial Acceptance			
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	21 Oct 2013	listed		
Dossier Evaluation	19 Sept 2013	MR		

MR: meets requirements

The table represents the status of relevant completed activities only.