WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Zophralen Solution for Injection 4 mg/2 mL [1]

Ondansetron (as hydrochloride dihydrate) 4 mg/2 mL solution for injection

Zophralen Solution for Injection 4 mg/2 mL was submitted in 2013 by DEMO S.A. to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the management of HIV/AIDS on 21 October 2013.

Information on the site(s) involved in the manufacture of the product and the API is available at the products listing information: https://extranet.who.int/prequal/medicines/ha597

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 Team: Medicines (PQTm), is based on the approval by the EOF (National Organisation for Medicines, Greece, https://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.

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 in hot and very humid areas, stability studies under the conditions defined for Climatic Zones IVb have been requested from the Applicant[4].

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:

[1] 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.

[2] https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs961-annex10-who-procedure-prequalification.pdf?sfvrsn=85029f47_2

[3] https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs986-annex5.pdf?sfvrsn=8aae767d_2

[4] https://extranet.who.int/prequal/sites/default/files/document_files/48%20Stability%20data%20SRA%20FPPs_March2016_newtempl.pdf

Glass and polypropylene ampoules:

- Do not store above 30°C. Store in the original package in order to protect from light.
- The shelf-life at this storage condition is 36 months.

This WHOPAR refers to the information available at the approving stringent regulatory authority's website resulting from the assessment of the quality, efficacy and safety as well as steps taken after approval.

https://services.eof.gr/human-search/view.xhtml?id=9bb4fa7566bc068ea070cc6877af4cae90cfea3a9feaf240ac58243388d199fd

For details on the uses of this product, for relevant efficacy and safety information see the summary of product characteristics and the patient information leaflet.

The English language version of the patient information leaflet, the summary of product characteristics and the labelling, as certified to be "EOF" approved texts, are included in this WHOPAR.

This WHOPAR for Zophralen is comprised of parts 2, 3. 4. 5 and 7.

Zophralen contains ondansetron. Its WHO recommended use is for the management of HIV/AIDS.

Summary of Prequalification Status for Zophralen Solution for Injection 4 mg/2 mL

	Initial Acceptance		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list	21 October 2013	listed	21 August 2024	listed
Dossier Evaluation	September 2013	MR	August 2024	requalified
PQ: prequalification MR: meets requirements				

The table represents the status of relevant completed activities only.