

WHO Prequalification Programme WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Vendal retard 10 mg-Filmdabletten ¹

Morphine hydrochloride 10 mg prolonged-release film-coated tablets

Vendal retard 10 mg film-coated tablets was submitted in 2014 by G.L. Pharma GmbH to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the treatment and management of HIV/AIDS related conditions on 12 December 2014.

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/ha636>

The “Procedure for prequalification of pharmaceutical products²” 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 Austrian Agency for Health and Food Safety (AGES, <http://www.ages.at/>) 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 Applicant⁴.

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

- Do not store above 25°C. Protect from moisture. Avoid excursions above 25°C.
- 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://www.basg.gv.at/en/> <https://aspreghister.basg.gv.at/aspreghister/faces/aspreghister.jspx>
MA number 1-19834)

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 "AGES" approved texts, are included in this WHOPAR.

This WHOPAR for Vendal retard 10 mg is comprised of parts 2, 3, 4, 5 and 7.

Vendal retard 10 mg film-coated tablets contains morphine hydrochloride trihydrate.

Its WHO recommended use is for the treatment and management of HIV/AIDS related conditions.

Summary of Prequalification Status for Vendal retard 10 mg

	Initial Acceptance		Requalification	
	Date	Outcome	Date	Outcome
Status on PQ list	12 December 2014	listed	16 July 2024	listed
Dossier Evaluation	December 2014	MR	June 2024	requalified
PQ: prequalification MR: meets requirements				

The table represents the status of relevant completed activities only.