WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Vendal retard 30 mg- film-coated tablets [1]

International Nonproprietary Name (INN):
Morphine hydrochloride 30mg Prolonged-Release Tablets

Abstract

Vendal retard 30 mg film-coated tablets, manufactured at G.L. Pharma GmbH is a prolonged release formulation that was submitted to be considered for prequalification in 2014 when the product was licensed / registered in Austria and subsequently accepted for the WHO list of prequalified products for the treatment of HIV/AIDS related conditions on 12 Dec 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 "Austrian Agency for Health and Food Safety" (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, stability studies under the conditions defined for Climatic Zones IVb have been requested from the Applicant.
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 25°C. The shelf-life at this storage condition is 60 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.ages.at/ . Austrian medicinal product index 1-19837, last accessed May 2017).
The English language version of the Patient Information Leaflet, the Summary of Product Characteristics and the labelling, which is a company authorized English translation of the approved Austrian texts, are included in this WHOPAR.

[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

Parts 2a, 2b, 3, 4, 5 and 7 of the WHOPAR for Vendal retard 30 mg film-coated tablets are included here.

Vendal retard 30 mg- film-coated tablets is a prolonged released formulation containing morphine hydrochloride. Its WHO recommended use is for the treatment of severe and most severe pain, refractory to other analgetics, in HIV/AIDS patients."
The most frequent adverse events observed during treatment with morphine hydrochloride were nausea, vomiting, dry mouth, constipation, miosis, and drowsiness.
The most serious adverse effects of morphine hydrochloride are bronchospasm, respiratory depression, bile tract spasms, hypersensitivity reactions and general asthenia up to syncope.

The efficacy and safety profile of morphine hydrochloride is well established based on the extensive clinical experience in the treatment of severe and most severe pain.

Summary of Prequalification Status for Vendal retard 30 mg film-coated tablets

	Initial Acceptance			
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	12 Dec 2014	listed		
Dossier Evaluation	03 Dec 2014	MR		

MR: meets requirements

The table represents the status of relevant completed activities only.