WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Exlutena 0.5mg tablets/ Exluton 0,5mg tablets[1]

International Nonproprietary Name (INN):
Lynestrenol 0.5mg Tablets

Abstract

Exlutena 0.5mg tablets, manufactured at N.V. Organon 5349 AB Oss, The Netherlands, was submitted to be considered for prequalification in 2009 when the product was licensed / registered in The Netherlands and subsequently accepted for the WHO list of prequalified products for reproductive health conditions in women on 02 June 2010.

The reference SRA changed from The Netherlands (MEB) to Sweden (MPA) in September 2019.

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 Swedisch Medical Products Agency ("Läkemedelsverket" https://lakemedelsverket.se/english/) 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 30°C. Avoid excursions above 30°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 (https://lakemedelsverket.se/LMF/Lakemedelsinformation/?nplid=19740510000012&type=product).

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 Swedish texts, are included in this WHOPAR.

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[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 Exlutena 0.5mg tablets are included here.

Exlutena 0.5mg tablets is a so called progestogen only contraceptive pill containing the synthetic hormone lynestrenol. It is indicated for contraception for women.
The most frequent adverse events observed during use of lynestrenol were headache, migraine, nausea, abdominal pain, weight increase, irregular bleeding, acne, chloasma and rash.
The most serious adverse effects of lynestrenol are hypersensitivity, thromboembolic disorders, (venous and arterial), hormone-dependent tumours (e.g. breast cancer) and depression, which can be serious and is a well-known risk factor for suicidal behaviour and suicide.

Summary of Prequalification Status for Exlutena 0.5mg tablets

	Initial Acceptance		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list,	02 June 2010	listed	12 Sept 2019	listed
Dossier Evaluation	17 May 2010	MR	12 Sept 2019	requalified

MR: meets requirements
The table represents the status of relevant completed activities only.