WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Noristerat 200mg, Solution for intramuscular injection[1]

Norethisterone Enantate 200 mg/ml Injection

Noristerat 200mg, solution for intramuscular injection was submitted in 2010 by Bayer Schering Pharma AG Berlin, Germany. to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for contraception for women on 05 October 2011.
After prequalification the name of the manufacturer was changed to Bayer AG, Berlin, Germany.
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/pqweb/medicine/3995

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 British "Medicines and Healthcare Products Regulatory Agency" (http://www.mhra.gov.uk/), 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:

- Do not store above 30°C. Protect from light.
- The shelf-life at this storage condition is 60 months.

This WHOPAR refers to the information available at the approving stringent regulatory authority's website (http://www.mhra.gov.uk/) resulting from the assessment of the quality, efficacy and safety as

[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/pqweb/sites/default/files/documents/48 Stability data SRA FPPs_March2016_newtempl.pdf

well as steps taken after approval:
(https://products.mhra.gov.uk/search/?search=00010%2F0548&page=1) (PL 00010/0548)

Parts 2, 5 and 7 of the WHOPAR for Noristerat are included here.

Noristerat is a so called progestogen-only contraceptive, containing the synthetic hormone norethisterone enantate. It is indicated for contraception for women and is administered via intramuscular injection.

The efficacy and safety profile of norethisterone enantate is well established based on the extensive clinical experience in female contraception.

Summary of Prequalification Status for Noristerat:

	Initial Acceptance		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list	05 October 2011	listed	28 September 2017	listed
Dossier Evaluation	01 October 2011	MR	12 July 2016	requalified

PQ: prequalification

MR: meets requirements

The table represents the status of relevant completed activities only.