WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Noristerat® 200 mg, solution for intramuscular injection[1]

Norethisterone enantate 200 mg/ml solution for intramuscular injection

Noristerat 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.

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/rh022

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 British "Medicines and Healthcare Products Regulatory Agency" (https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency), 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

[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

This WHOPAR refers to the information available at the approving stringent regulatory authority's website (https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency) resulting from the assessment of the quality, efficacy and safety as well as steps taken after approval.

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 as approved by the British MHRA(https://products.mhra.gov.uk/search/?search=Noristerat&page=1&doc=Spc%7CPil%7CPar&rerouteType=0 PL 00010/0548)

This WHOPAR for Noristerat is comprised of parts 2, 5 and 7.

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.

Summary of Prequalification Status for
Noristerat 200 mg, solution for intramuscular injection

	Initial Acceptance		**Requalification**		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list	05 Oct 2011	listed	28 Sept 2017	listed	May 2025	listed
Dossier Evaluation	Oct 2011	MR	July2016	requalified	May 2025	requalified
PQ: prequalification MR: meets requirements						

The table represents the status of relevant completed activities only.