WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Implanon NXT 68 mg implant for subdermal use [1]

Etonogestrel 68 mg Implant (NXT)

Implanon NXT, 68 mg implant for subdermal use was submitted in 2013 by N V Organon to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for contraception for women on 23 May 2013.
Information on the sites involved in the manufacture of the product and the API is available at the products listing information (https://extranet.who.int/pqweb/medicine/4002).

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 Dutch Medicines Evaluation Board "CBG-MEB" (https://english.cbg-meb.nl/) 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. Store in the original blister package.
- The shelf-life at this storage condition is 60 months. Implanon NXT should not be inserted after the expiry date as indicated on the primary package.

[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

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. (http://www.cbg-meb.nl/ https://english.cbg-meb.nl/sections/marketing-authorisation-medicines-for-human-use RVG 21168)

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 "CBG-MEB" approved texts, are included in this WHOPAR.
This WHOPAR for Implanon NXT is comprised of parts 2, 3, 4, 5 and 7.

Implanon NXT contains the synthetic hormone etonogestrel and is indicated for long-acting, reversible contraception for women. It is an implant preloaded in an applicator.

The efficacy and safety profile of etonogestrel is well established based on the extensive clinical experience for contraception in women.

Summary of Prequalification Status for Implanon NXT, 68 mg implant for subdermal use

	Initial Acceptance		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list,	23 May 2013	listed	20 June 2023	listed
Dossier Evaluation	March 2013	MR	June 2023	requalified

PQ: prequalification

MR: meets requirements

The table represents the status of relevant completed activities only.