WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Jadelle sine inserter 2 x 75 mg implant [1]

Levonorgestrel 75 mg implant (without inserter)

Jadelle sine inserter 2 x 75 mg implant was submitted in 2009 by Bayer Oy. to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for female contraception on 23 September 2009.
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/3992).

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 Finish Medicine Agency "fimea" (https://www.fimea.fi/), 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.
- 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 (https://www.fimea.fi/) resulting from the assessment of the quality, efficacy and safety as well as steps taken after approval.

[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

(http://www.fimea.fi/web/en/databases_and_registeries/fimeaweb, marketing authorization number: 17098)
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 "fimea" approved texts, are included in this WHOPAR.
This WHOPAR for Jadelle sine inserter 2 x 75 mg implant is comprised of
parts 2, 3. 4. 5 and 7.

Jadelle Sine Inserter is a so-called progestogen-only contraceptive, containing the synthetic hormone levonorgestrel. It is indicated for long-acting, reversible contraception for women and is applied via implantation of the rods.

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

Summary of Prequalification Status for Jadelle sine inserter 2 x 75 mg implant

	Initial Acceptance		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list,	23 Sept 2009	listed	01 June 2016	listed
Dossier Evaluation	22 July 2009	MR	25 April 2016	MR

MR: meets requirements