WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

INTELENCE 25 mg tablets[1]

Etravirine 25 mg tablets

INTELENCE 25 mg tablets was submitted in 2013 by Janssen Cilag International NV to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the treatment of HIV/AIDS on 21 October 2013.

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/ha600

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 European Medicines Agency (EMA http://www.ema.europa.eu/ema/) 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:

[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

- Do not store above 30°C. Store in the original bottle. Keep the bottle tightly closed in order to protect from moisture. Do not remove the desiccant pouches
- The shelf-life at this storage condition is 24 months. In-use period: 8 weeks

Based on the above, the WHOPAR for INTELENCE refers for parts 1, 3, 4, 5, 6 and 8 to the previously issued public assessment report as follows:

WHOPAR part		**Reference**[5]
Part 1	Summary for the Public	Intelence, INN-etravirine (europa.eu)
Part 3	Package Leaflets	intelence-epar-product-information_en.pdf (europa.eu)
Part 4	Summaries Product Characteristics	intelence-epar-product-information_en.pdf (europa.eu)
Part 5	Labelling	intelence-epar-product-information_en.pdf (europa.eu)
Part 6	Discussion	INTELENCE; INN: etravirine (europa.eu)
Part 8	Steps taken following Authorisation	Intelence, INN-etravirine (europa.eu)

Parts 2 and 7 of the WHOPAR for INTELENCE are included here.

Summary of Prequalification Status for INTELENCE 25 mg tablets

	Initial Acceptance		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list	21 October 2013	listed	26 November 2023	listed
Dossier Evaluation	16 August 2013	MR	14 November 2023	MR

PQ: prequalification
MR: meets requirements

The table represents the status of relevant completed activities only.

[5] Intelence | European Medicines Agency (europa.eu)
EMEA/H/C/000900