

WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Enskyce¹

Desogestrel/Ethinylestradiol 150µg/30µg Tablets + inactive tablets

Enskyce was submitted in 2013 by Lupin Limited. to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for female contraception on 21 October 2013.

Information on the site(s) involved in the manufacture of the product and the APIs is available at the products listing information (<https://extranet.who.int/prequal/medicines/rh044>)

The “Procedure for prequalification of pharmaceutical products²” 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 “U.S. Food and Drug Administration” (<http://www.fda.gov/>), 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 Applicant⁴.

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. Avoid excursions above 30°C.
- The shelf-life at this storage condition is 24 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 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 Prescribing Information as approved by USFDA: ([Drugs@FDA: FDA-Approved Drugs](#) (Application No: 201887))

The English language version of the Prescribing Information and the labelling, as certified to be FDA approved texts, are included in this WHOPAR.

This WHOPAR for Enskyce is comprised of parts 2, 3, 4, 5 and 7.

Enskyce contains the synthetic hormones desogestrel and ethinylestradiol.

Its WHO recommended use is for contraception for women.

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

Summary of Prequalification Status for Enskyce

| | Initial Acceptance | | Requalification | |
|--|--------------------|---------|-----------------|-------------|
| | Date | Outcome | Date | Outcome |
| Status on PQ list | 21 October 2013 | listed | 08 March 2023 | listed |
| Dossier Evaluation | September 2013 | MR | February 2023 | requalified |
| PQ: prequalification MR: meets requirements | | | | |

The table represents the status of relevant completed activities only.