

WHO Prequalification Programme WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Nicorette Novum 15 mg/16 hours transdermal patch¹

Nicotine 15 mg/16 hours transdermal patch

Nicorette Novum 15 mg/16 hours transdermal patch was submitted in 2024 by McNeil Sweden AB. to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for treatment of disorders caused by use of tobacco on 04 April 2024.

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/td004>

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 (PQT/MED), is based on the approval by the Swedish Medical Products Agency “lakemedelsverket” (<https://www.lakemedelsverket.se/en>), 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.

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=8aac767d_2

⁴ https://extranet.who.int/prequal/sites/default/files/document_files/48%20Stability%20data%20SRA%20FPPs_March2016_newtempl.pdf

Based on the submitted stability data WHO PQT/MED 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 24 months

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

[Nicorette Novum 15 mg/16 timmar depotplåster | Läkemedelsverket \(lakemedelsverket.se\)](#)

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 "Läkemedelsverket" approved texts, are included in this WHOPAR.

This WHOPAR for Nicorette Novum 15 mg/16 hours is comprised of parts 2, 3, 4, 5 and 7.

Nicorette Novum 15 mg/16 hours contains nicotine. Its WHO recommended use is for treatment of disorders caused by use of tobacco.

Summary of Prequalification Status for Nicorette Novum 15 mg/16 hours transdermal patch

Initial acceptance	Date	Outcome
Status on PQ list	04 April 2024	listed
Quality	March 2024	MR
PQ: prequalification MR: meets requirements		

The table represents the status of relevant completed activities only.