WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Paxlovid 150 mg /100 mg film-coated tablets[1]

Nirmatrelvir150mg tablets + Ritonavir 100mg tablets

Paxlovid 150 mg/100 mg film-coated tablets was submitted in January 2022 by Pfizer Limited to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the treatment of Coronavirus disease 2019 (Covid-19) on 22 April 2022. Information on the site(s) involved in the manufacture of the product and the API(s) is available at the products listing information: https://extranet.who.int/prequal/medicines/cv007

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 Conditional Marketing Authorisation granted by the Great Britain Medicines and Healthcare products Regulatory Agency "MHRA" (https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency), 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].

[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

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. Do not refrigerate or freeze.
- 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

https://products.mhra.gov.uk/search/?search=Paxlovid&page=1 PLGB 00057/1710)

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 as approved by MHRA

https://products.mhra.gov.uk/search/?search=Paxlovid&page=1

This WHOPAR for Paxlovid is comprised of parts 2, 5 and 7.

Paxlovid contains nirmatrelvir 150 mg film-coated tablets coblistered with ritonavir 100 mg film-coated tablets.

Its WHO recommended use is for the treatment of COVID-19 in adults who do not require supplemental oxygen and who are at increased risk for progression to severe COVID-19.

The efficacy and safety profile of nirmatrelvir/ritonavir in the treatment of Coronavirus disease 2019 (Covid-19) has been established in a randomised controlled trial with 2085 patients.

Summary of Prequalification Status for Paxlovid 150 mg/100 mg film-coated tablets

Initial acceptance	**Date**	**Outcome**
Status on PQ list	22 April 2022	listed
Quality	February 2022	MR

MR: meets requirements

The table represents the status of relevant completed activities only.