WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Peyona[1]

Caffeine citrate 20 mg/mL (3mL) solution for infusion and oral solution

Peyona was submitted in 2026 by Chiesi Farmaceutici S.p.A. to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for prevention and treatment of apnoea in preterm infants on 10 July 2026.

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/ap003

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 (PQT/MED), is based on the approval by the European Medicines Agency (EMA https://www.ema.europa.eu/en/medicines) 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 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 36 months

Based on the above, the WHOPAR for Peyona **(**former trade name: Nymusa) 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	https://www.ema.europa.eu/en/documents/overview/peyona-epar-medicine-overview_en.pdf
Part 3	Package Leaflet	https://www.ema.europa.eu/en/documents/product-information/peyona-epar-product-information_en.pdf
Part 4	Summary of Product Characteristics	https://www.ema.europa.eu/en/documents/product-information/peyona-epar-product-information_en.pdf
Part 5	Labelling	https://www.ema.europa.eu/en/documents/product-information/peyona-epar-product-information_en.pdf
Part 6	Discussion	https://www.ema.europa.eu/en/documents/assessment-report/nymusa-epar-public-assessment-report_en.pdf
Part 8	Steps taken following Authorisation	https://www.ema.europa.eu/en/documents/procedural-steps-after/peyona-epar-procedural-steps-taken-scientific-information-after-authorisation_en.pdf

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

Peyona contains caffeine citrate. Its WHO recommended use is to prevent and treat apnoea of prematurity and support extubation of preterm infants born before 34 weeks' gestation.

Summary of Prequalification Status for Peyona

Initial acceptance	**Date**	**Outcome**
Status on PQ list	10 July 2026	listed
Quality	June 2026	MR
PQ: prequalification MR: meets requirements		

The table represents the status of relevant completed activities only.

[5] https://www.ema.europa.eu/en/medicines/human/EPAR/peyona