WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Caffeine Citrate 10mg/ml Solution for Injection [1]

Caffeine citrate 10 mg/mL solution for injection (1 mL ampoule)

Caffeine Citrate 10mg/ml Solution for Injection was submitted in 2025 by Ethypharm UK Ltd. to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the prevention and treatment of apnoea in preterm infants on 05 December 2025.

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/ap002

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 United Kingdom Medicines & 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].

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:

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[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. Do not freeze.
- The shelf-life at this storage condition is 36 months

This WHOPAR refers to the information available at the approving stringent regulatory authority's website (https://www.gov.uk/guidance/find-product-information-about-medicines) 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 summary of product characteristics and the patient information leaflet as approved by MHRA, (which use this structure of product information and publishes it in English on their websites)

https://products.mhra.gov.uk/search/?search=PL+01883%2F0344&page=1 (PL 01883/0344)

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

Caffeine Citrate 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 Caffeine Citrate 10mg/ml Solution for Injection

Initial acceptance	**Date**	**Outcome**
Status on PQ list	05 December 2025	listed
Quality	November 2025	MR
PQ: prequalification MR: meets requirements		

The table represents the status of relevant completed activities only.