WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Benzetacil 2.400.000 UI powder and solvent for suspension for injection[1]

Benzathine Benzylpenicillin 2.4 million IU powder and solvent for suspension

Benzetacil 2.400.000 UI powder and solvent for suspension for injection was submitted in 2022 by LABORATORIO REIG JOFRE, S.A to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the treatment of reproductive health conditions on 21 March 2023.
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/pqweb/medicine/4449

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 Spanish Agency of Medicines and Medical Devices "AEMPS" (Agencia Española de Medicamentos y Productos Sanitarios (aemps.gob.es) / 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:

[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/pqweb/sites/default/files/documents/48 Stability data SRA FPPs_March2016_newtempl.pdf

- Do not store above 30°C. Protect from moisture. Store in the original package in order to protect from light.
- The shelf-life at this storage condition is 24 months
- Shelf-life after reconstitution: The reconstituted product should be used immediately for intramuscular administration.

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://cima.aemps.es/cima/publico/lista.html MA number 22959)

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.
https://cima.aemps.es/cima/publico/detalle.html?nregistro=22295
The English language version of the patient information leaflet, the summary of product characteristics and the labelling, as certified to be "AEMPS" approved texts, are included in this WHOPAR.

This WHOPAR for Benzetacil 2.400.000 UI is comprised of parts 2, 3, 4, 5 and 7.

Benzetacil 2.400.000 UI contains benzathine benzylpenicillin.
Its WHO recommended use is for the treatment of maternal syphilis.

The efficacy and safety profile of benzathine benzylpenicillin is well established based on the extensive clinical experience for the treatment of reproductive health.

Summary of Prequalification Status for Benzetacil 2.400.000 UI

Initial acceptance	**Date**	**Outcome**
Status on PQ list	21 March 2023	listed
Quality	March 2023	MR
PQ: prequalification MR: meets requirements		

The table represents the status of relevant completed activities only.