WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Dexamethasone Phosphate/DEMO, 4 mg/mL, Solution for injection (2 mL)[1]

Dexamethasone phosphate (as sodium) 8mg/2mL solution for injection

Dexamethasone Phosphate/DEMO, 4 mg/mL, Solution for injection (2 mL) was submitted in 2021 by Demo S.A. Pharmaceutical Industry, 21st km National Road Athens-Lamia, 145 68 Krioneri, Attiki, Greece. to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the management of conditions responsive to parenteral treatment with a potent glucocorticoid on 29 September 2021.
Information on the site(s) involved in the manufacture of the product and the API is available at: https://extranet.who.int/pqweb/medicine/4372

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 Greek authority "National Organization for Medicines" (www.eof.gr) 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 25°C. Keep the ampoule in the outer carton in order to protect from light. Do not refrigerate or freeze. Avoid excursions above 25°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.
(https://www.eof.gr/web/guest Reg. No. in Greece: 22062/17-03-2021 GR)

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 by the Greek "National Organization for Medicines, eof". approved texts are included in this WHOPAR.

This WHOPAR for Dexamethasone Phosphate/DEMO, 4 mg/mL, Solution for injection (2 mL) is comprised of parts 2, 3. 4. 5 and 7.

Dexamethasone Phosphate/DEMO, 4 mg/mL, Solution for injection (2 mL) contains dexamethasone phosphate (as sodium). Its WHO recommended use is in a wide range of conditions for its anti-inflammatory and immunosuppressant effects.

The efficacy and safety profile of dexamethasone is well established based on extensive clinical experience in the treatment of a wide range of conditions.

Summary of Prequalification Status for
Dexamethasone Phosphate/DEMO, 4 mg/mL, Solution for injection (2 mL)

Initial acceptance	**Date**	**Outcome**
Status on PQ list	29 September 2021	listed
Quality	September 2021	MR

PQ: prequalification
MR: meets requirements

The table represents the status of relevant completed activities only.