WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Ofost 10 IU/ml concentrate for solution for infusion or solution for intramuscular injection [1]

Oxytocin 10 IU/ml solution injection

Ofost 10 IU/ml concentrate for solution for infusion or solution for intramuscular injection was submitted in 2025 by AS GRINDEKS, Lativa, to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for facilitating reproductive health on 27 September 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/rh110

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 Health Products Authority of Ireland (HPRA, https://www.hpra.ie/) 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:

- Store in a refrigerator (2 ºC – 8 ºC). Do not freeze.
- The shelf-life at this storage condition is 60 months.

[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

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.hpra.ie/find-a-medicine/for-human-use/authorised-medicines/details/36864 (Licence number PA22992/001/002)

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 the Irish HPRA
https://www.hpra.ie/find-a-medicine/for-human-use/authorised-medicines/details/36864

This WHOPAR for Ofost 10 IU/ml is comprised of parts 2, 5 and 7.

Ofost 10 IU/ml contains oxytocin. Its WHO recommended use is for the management of labour and complications of pregnancy.

Summary of Prequalification Status for Ofost 10 IU/ml concentrate for solution for infusion or solution for intramuscular injection

Initial acceptance	**Date**	**Outcome**
Status on PQ list	27 September 2025	listed
Quality	September 2025	MR
PQ: prequalification MR: meets requirements		

The table represents the status of relevant completed activities only.