WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Oxytocin 10 IU/ml concentrate for solution for infusion[1]

International Nonproprietary Name (INN):
Oxytocin 10 IU/ml solution for injection

Oxytocin 10 IU/ml concentrate for solution for infusion, manufactured at PANPHARMA GmbH, Bunsenstrasse 4, 22946 Trittau, Germany, was submitted to be considered for prequalification in 2021 and subsequently accepted for the WHO list of prequalified products for facilitating reproductive health on 01 July 2021.

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 a stringent regulatory authority (SRA), the United Kingdom Medicines and Healthcare products Regulatory Agency "MHRA" (http://www.gov.uk/mhra), 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°C – 8°C). Keep the ampoules in the outer carton in order to protect from light.
>
> The shelf-life at this storage condition is 36 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] http://www.who.int/medicines/areas/quality_safety/quality_assurance/TRS961_Annex10.pdf
[3] http://www.who.int/medicines/areas/quality_safety/quality_assurance/TRS986annex5.pdf?ua=1
[4] https://extranet.who.int/pqweb/sites/default/files/documents/48%20Stability%20data%20SRA%20FPPs_March2016_newtempl.pdf

This WHOPAR refers to the information available at the approving (www.gov.uk/mhra) stringent regulatory authority's website 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 and for side effects and warnings, see the summary of product characteristics and the patient information leaflet as approved by UK MHRA: https://products.mhra.gov.uk/search/?search=PL+44124%2F0024&page=1 (PL 44124/0024)

Parts 2, 5 and 7 of the WHOPAR for Oxytocin 10 IU/ml concentrate for solution for infusion are included here.

Oxytocin 10 IU/ml concentrate for solution for infusion contains oxytocin.
Its WHO recommended use is for the management of labour, prevention and treatment of postpartum haemorrhage and for the management of complications of pregnancy.

The efficacy and safety profile of oxytocin. is well established based on the extensive clinical experience in women for the indicated conditions.

Summary of Prequalification Status for
Oxytocin 10 IU/ml concentrate for solution for infusion

Initial acceptance	**Date**	**Outcome**
Status on PQ list	01 July 2021	listed
Quality	June 2021	MR

MR: meets requirements

The table represents the status of relevant completed activities only.