WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[RH079 trade name]*

International Nonproprietary Names (INN) /strength/pharmaceutical form:
Oxytocin 10 IU/mL solution for injection

Abstract

[RH079 trade name], manufactured at HBM Pharma s.r.o, Martin, Slovakia and at UAB Santonika, Kaunas, Lithuania was included in the WHO list of prequalified products for facilitating reproductive health on 14 October 2019.

[RH079 trade name] is indicated for the management of labour, prevention and treatment of postpartum haemorrhage and for the management of complications of pregnancy. Detailed information on the use of this product is described in the summary of product characteristics (SmPC), which can be found in this WHOPAR.

The active pharmaceutical ingredient (API) of [RH079 trade name] is oxytocin. The API is well established and documented for the management of labour and complications of pregnancy.

The efficacy and safety profile of [RH079 trade name] has been established on the basis of extensive clinical experience in women for the indicated conditions.

For details on the uses of this product and for side effects and warnings, see Part 4 of this WHOPAR (summary of product characteristics).

On the basis of data submitted and public information on the use of oxytocin for women in reproductive health indications, the team of assessors advised that [RH079 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [RH079 trade name] in the list of prequalified medicinal products.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

Summary of Prequalification Status for [RH079 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	14 Oct 2019	listed
Quality	30 Sept 2019	MR
Bioequivalence	NA	NA
Safety, Efficacy	NA	NA
GMP(re-)inspection		
API	NA	NA
FPP (UAB Santonika)	04 June 2018	MR
FPP (HBM Pharma s.r.o.)	29 June 2018	MR
FPP (JSC Grindeks)	14 Dec 2018	MR
GCP/GLP (re-)inspection	NA	NA

MR: meets requirements
NA: not applicable, not available