WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Santocyn* 10 units/ml solution for injection

International Nonproprietary Names (INN):
Oxytocin

Abstract

Santocyn, manufactured at PT Sanbe Farma, Bandung, Indonesia was accepted for the WHO list of prequalified products for facilitating reproductive health on 30 Jun 2017.

Santocyn 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 Santocyn is oxytocin. The API is well established and documented for the management of labour and complications of pregnancy.

The most frequent adverse events that follow use of oxytocin include headache, changes in heart rate, nausea and vomiting.

The most important adverse effects of oxytocin include arrhythmia, rupture of the uterus, water intoxication and disseminated intravascular coagulation.

The efficacy and safety profile of Santocyn has been established on the basis of extensive clinical experience in women for the indicated conditions.

On the basis of data submitted and public information on the use of oxytocin for women in reproductive health indications, the team of assessors accepted Santocyn for the list of prequalified medicinal products.

* 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.

Summary of Prequalification Status for Santocyn:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list (i.e. date of listing)	30 Jun 2017	listed				
Dossier Evaluation (Quality assurance)						
Quality	19 Oct 2016	MR				
Bioequivalence	NA	NA				
Safety, Efficacy	NA	NA				
Inspection Status						
GMP(re-)inspection						
API	NA[†]	MR				
FPP	17 Feb 2017	MR				
GCP/GLP inspection[‡]	NA	NA				

MR: Meets Requirements
NA: Not applicable, not available

[†] The API manufacturer holds a valid certificate of suitability issued by the European Directorate for the Quality of Medicines (EDQM) on 10 Jan 2014
[‡] Not inspected for GCP/GLP. No bioequivalence study was required for this parenteral product