WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[IN018 trade name]*

Oseltamivir (as phosphate) 30 mg Capsules

[IN018 trade name], manufactured at MSN Laboratories Private Limited, Nandigama, Telangana, India, was included in the WHO list of prequalified medicinal products for the treatment of influenza on 14 July 2020.

[IN018 trade name] is indicated for treatment and post-exposure prophylaxis of influenza. 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 of [IN018 trade name] is oseltamivir (as phosphate).

The efficacy and safety of oseltamivir are well established based on extensive clinical experience in the treatment of influenza.

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 oseltamivir in influenza, the team of assessors advised that [IN018 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [IN018 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [IN018 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	14 July 2020	listed
Quality	03 July 2020	MR
Bioequivalence	08 July 2020	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	16 October 2015	MR
FPP	27 May 2020	MR*
GCP/GLP (re-)inspection	NA	NA

MR: meets requirements

MR*: desk review (based on recent inspection reports)
NA: not applicable, not available

The table represents the status of relevant completed activities only.

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