WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[NT007 trade name][*]

Ivermectin 3 mg tablets

[NT007 trade name], manufactured at Laboratorios Liconsa, S.A, Azuqueca de Henares, Guadalajara, Spain, was included in the WHO list of prequalified medicinal products for the treatment of parasitic infestation on 01 July 2021.

[NT007 trade name] is currently indicated for helminthiases and ectoparasitic infestations. 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 [NT007 trade name] is ivermectin.

The efficacy and safety of ivermectin are well established based on extensive clinical experience in the treatment of helminthiases and ectoparasitic infestations.

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 ivermectin, the team of assessors advised that [NT007 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [NT007 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [NT007 trade name]:

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

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

Initial acceptance	**Date**	**Outcome**
Status on PQ list	01 July 2021	listed
Pharmaceutical quality	31 May 2021	MR
Bioequivalence	04 June 2021	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	21 June 2021	MR*
FPP	19 March 2019	MR*
GCP/GLP (re-)inspection	23 February 2018	MR

API: active pharmaceutical ingredient
FPP: finished pharmaceutical product
GCP: good clinical practice [quality standard]
GLP: good laboratory practice [quality standard]
GMP: good manufacturing practice [quality standard]
MR: meets requirements
MR*: desk review (based on recent inspection reports)
NA: not applicable, not available
PQ: prequalification