

**WHO Prequalification Programme**  
**WHO PUBLIC ASSESSMENT REPORT (WHOPAR)**

**[CV010 trade name]\***

Molnupiravir 200 mg capsules

[CV010 trade name], manufactured at Emcure Pharmaceuticals Ltd, Pune, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of COVID-19 on 26 December 2022.

[CV010 trade name] is indicated for treating non-severe COVID-19 in adults who are at high risk of their disease becoming severe. 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 [CV010 trade name] is molnupiravir.

The efficacy and safety of molnupiravir are well established based on extensive clinical experience in the treatment of COVID-19.

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 molnupiravir in COVID-19, the team of assessors advised that [CV010 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [CV010 trade name] in the list of prequalified medicinal products.

**Summary of prequalification status for [CV010 trade name]:**

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

<b>Initial acceptance</b>	<b>Date</b>	<b>Outcome</b>
<b>Status on PQ list</b>	26 December 2022	listed
Quality	23 November 2022	MR
Bioequivalence	24 November 2022	MR
Safety, efficacy	NA	NA
<b>GMP (re-)inspection</b>		
API	3 August 2020	MR*
API	2 March 2022	MR*
FPP	15 February 2019	MR
<b>GCP/GLP (re-)inspection</b>		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		

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