

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

### **[HA713 trade name]\***

Dolutegravir (as sodium) /lamivudine/ tenofovir disoproxil fumarate 50 mg/ 300 mg/  
300 mg film-coated tablets

[HA713 trade name] manufactured at at Macleods Pharmaceuticals Limited, Mumbai, India was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 21 May 2020.

[HA713 trade name] is indicated for the treatment of human immunodeficiency virus (HIV) infection in adults and adolescents weighing at least 30 kg. 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 ingredients of [HA713 trade name] are dolutegravir (as sodium), lamivudine and tenofovir disoproxil fumarate.

The efficacy and safety profile of dolutegravir (as sodium), lamivudine and tenofovir disoproxil fumarate are well established based on extensive clinical experience in the treatment of HIV/AIDS.

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 [HA713 trade name] in the treatment of HIV/AIDS, the team of assessors advised that [HA713 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA713 trade name] in the list of prequalified medicinal products.

### **Summary of prequalification status for [HA713 trade name]:**

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

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

Initial acceptance	Date	Outcome
Status on PQ list	21 May 2020	listed
Pharmaceutical quality	22 April 2020	MR
Bioequivalence	27 April 2020	MR
Safety, efficacy	NA	NA
<b>GMP (re-)inspection</b>		
API	01 February 2019	MR*
FPP	23 October 2019	MR
<b>GCP/GLP (re-)inspection</b>	14 July 2017	MR
<div> <div> API: active pharmaceutical ingredient  FPP: finished pharmaceutical product  GCP: good clinical practice [quality standard]  GLP: good laboratory practice [quality standard] </div> <div> GMP: good manufacturing practice [quality standard]  MR: meets requirements  MR*: desk review (based on recent inspection reports)  NA: not applicable, not available  PQ: prequalification </div> </div>		