WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA694 trade name]*

Dolutegravir (as sodium) 50 mg film-coated tablets

[HA694 trade name], manufactured at Shanghai Desano Bio-Pharmaceutical Co Ltd, Shanghai, China, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 2 November 2020.

[HA694 trade name] is indicated ,in combination with other antiretroviral medicines, for the treatment of HIV infection in patients weighing at least 20 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 ingredient of [HA694 trade name] is dolutegravir sodium. The efficacy and safety of dolutegravir sodium 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 dolutegravir in the treatment of HIV/AIDS, the team of assessors advised that [HA694 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA694 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA694 trade name]:

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

Initial acceptance	**Date**	**Outcome**
Status on PQ list	2 November 2020	listed
Pharmaceutical quality	27 March 2019	MR
Bioequivalence	23 April 2019	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	18 January 2019	MR
FPP	24 September 2020	MR*
GCP/GLP (re-)inspection	29 September 2017	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.