WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Entecavir Tablets USP, 0.5 mg[1]

Entecavir (as monohydrate) 0.5 mg tablet

Entecavir Tablets USP, 0.5 mg was submitted in 2022 by BrightGene Bio-Medical Technology Co., Ltd, China. to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the treatment of chronic hepatitis B virus infection on 22 March 2022.
Information on the site(s) involved in the manufacture of the product and the API is available at the products listing information: https://extranet.who.int/prequal/medicines/hp031.

The "Procedure for prequalification of pharmaceutical products[2]" defines specific evaluation mechanisms for products approved by regulatory authorities, which apply similar stringent standards for quality, safety and efficacy as those required by WHO.

The prequalification of this product by the WHO Prequalification Team: Medicines (PQTm), is based on the approval by the American U.S. Food and Drug Administration (USFDA https://www.fda.gov/) in line with the "Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities" [3].

Hence, no assessment of the data underlying this approval has been undertaken within the WHO Prequalification Programme.
However, according to the SRA guideline WHO may request additional data when considered necessary for the safe use of the product in regions relevant for prequalified products and such information may be included in the WHOPAR as a separate piece of information. In order to safeguard product quality throughout its entire intended shelf-life in hot and very humid areas, stability studies under the conditions defined for Climatic Zones IVb have been requested from the Applicant[4].

Based on the submitted stability data WHO PQTm considers the following storage condition appropriate for the product when distributed in regions with zone III, IVa and IVb climatic conditions, based on available stability information:

- Do not store above 30°C. Keep the bottle tightly closed and protect from light.
- The shelf-life at this storage condition is 24 months.

[1] Trade names are not prequalified by WHO. This is the National Medicines Regulatory Authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.
[2] https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs961-annex10-who-procedure-prequalification.pdf?sfvrsn=85029f47_2
[3] https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs986-annex5.pdf?sfvrsn=8aae767d_2
[4] https://extranet.who.int/prequal/sites/default/files/document_files/48%20Stability%20data%20SRA%20FPPs_March2016_newtempl.pdf

This WHOPAR refers to the information available at the approving stringent regulatory authority's website resulting from the assessment of the quality, efficacy and safety as well as steps taken after approval.
(https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=212126 (ANDA: 212126)

For details on the uses of this product, for relevant efficacy and safety information, see the Prescribing Information as approved by USFDA*:*
https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=212126
An English version of the prescribing information and the labeling as certified to be USFDA approved texts is included in this WHOPAR,

This WHOPAR for Entecavir Tablets USP, 0.5 mg is comprised of parts 2, 3,4, 5 and 7.

Entecavir Tablets USP, 0.5 mg contains entecavir (as monohydrate). Its WHO recommended use is for the treatment of chronic hepatitis B virus infection.

Summary of Prequalification Status for Entecavir Tablets USP, 0.5 mg

Initial acceptance	**Date**	**Outcome**
Status on PQ list	22 March 2022	listed
Quality	March 2022	MR
PQ: prequalification MR: meets requirements		

The table represents the status of relevant completed activities only.