Lenacapavir Regulatory Approvals

20 approvals, 7 pending approvals as of October 2026

European Medicines Agency (EMA)

LEN has also been reviewed under the "EU-Medicines for all" (M4All) process and WHO's Collaborative Registration Procedure (CRP) in order to help national regulators in LMICs accelerate their review. This has significantly shortened review time compared to previous PrEP products.

Canada
United States
Mexico
United Kingdom
Switzerland
Ukraine
Peru
Brazil
Nigeria
Ethiopia
Uganda
Kenya
Rwanda
Tanzania
Malawi
Zambia
Mozambique
Namibia
Zimbabwe
Botswana
Eswatini+
South Africa
Lesotho+
Vietnam
Thailand
Philippines
Australia

Approved
Pending

+Eswatini and Lesotho use an alternate pathway for regulatory approval - approval from the South African Health Products Regulatory Authority (SAHPRA) and pre-qualification from the World Health Organization (WHO) to authorize an Import License.

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October 2026