

WATCHLIST

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CLINICAL RELEVANCE

Doravirine is approved for HIV treatment as a once-daily oral regimen in combination with other ARVs, and is currently being in developed in combination with islatravir. Doravirine has shown efficacy and safety in children starting from 4 weeks of age. Doravirine has not yet been included in WHO treatment guidelines.

SERVICE DELIVERY ENABLERS

DOR's current companion drugs for HIV treatment are TDF/3TC (recommended by WHO with DTG and widely available in LMICs) and possibly islatravir, with which it is still in development. These oral daily regimens have no particular health system and infrastructure needs compared with the existing standard of care TDF/3TC/DTG.



MANUFACTURING

A spray drying process is adopted for the tablets. No challenges with respect to excipients or final packaging. No special requirements with respect to manufacturing facilities. Shelf life is 2.5 years at room temperature.

DISEASE BURDEN

In 2022, 39 million people globally were living with HIV and 1.3 million people became newly infected, most of which occurred in LMICs.

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TREATMENT

INTELLECTUAL PROPERTY LANDSCAPE

Primary patents on doravirine compound and its combinations with other anti-HIV agents or antivirals have been filed in many LMICs and are expected to expire in 2031. In few countries, the patent term may be extended by another five years, until 2036. While bilateral voluntary licences have been granted to generic manufacturer for 86 countries, public information on such licences is limited.

REGULATORY

Product approved by stringent regulatory authorities. Potential sublicensees of doravirine could rely on mechanisms like USFDA Para III, Swissmedic MAGHP or EU-M4all for quality assurance. Bioequivalence studies are necessary. Biowaivers will not be an option.

MARKET



Availability and affordability in LMICs is very low, as doravirine is generally not provided in most treatment programs.

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