

Announcement Vemlidy® (tenofovir alafenamide)

Regarding the exceptional provision of the medication with packaging materials and a package insert in English.

Gilead Sciences Farmacêutica do Brasil Ltda. (Gilead) clarifies that, in response to a request from the Ministry of Health and with a view to maintaining regular service to the public health network, as well as the continuity of Hepatitis B treatments, the batch of the drug **Vemlidy®** (tenofovir alafenamide) in the specifications described below, it will be supplied exceptionally with packaging materials and package insert in English.

To this end, the Ministry of Health submitted to the Health Surveillance Agency (ANVISA) a request for authorization, on an exceptional basis, for the import of the medicine Vemlidy® with packaging materials and package insert in the English language. This request was approved by the Agency's Collegiate Board of Directors in the <u>Deliberative Circuit</u> – CD 289/2024.

In the table below, Gilead details the batch and presentation description of the medicine involved in this exceptional authorization.

Vemlidy® (tenofovir alafenamide hemifumarate)	
Batch	Description of the presentation
042429	25 MG COM REV CT FR PLAS OPC X 30

It is also worth noting that Gilead has made copies of the package insert available in Portuguese so that the document can be supplied with the medicine bottles. Vemlidy® package insert can also be accessed through the <u>ANVISA</u> Electronic Information Sheet.