

Biktarvy® (BIC/FTC/TAF)

BIC Dissociation Half-Life

This document is in response to your request for information regarding Biktarvy® (bictegravir/emtricitabine/tenofovir alafenamide [BIC/FTC/TAF]) and the dissociation half-life of BIC.

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The full indication, important safety information, and boxed warnings are available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/biktarvy/biktarvy_pi.

Non-Clinical Data on BIC Dissociation Half-Life

In Vitro Dissociation Half-Life

Long residence times of INSTIs on the integrase-DNA complex have been correlated with potent antiretroviral activity and a high barrier to resistance in vitro.¹ The dissociation kinetics of ³H-labelled BIC, DTG, EVG, and RAL from wild-type or G140S/Q148H mutant HIV-1 integrase-DNA complexes were measured. The results showed that BIC had the longest dissociation half-life from wild-type HIV-1 integrase-DNA complexes (2-fold longer than DTG; BIC, 38 hours [reference]; DTG, 16 hours, $P=0.017$; EVG, 1.5 hours, $P=0.0006$; RAL, 5.2 hours, $P=0.003$) and from G140S/Q148H mutant integrase-DNA complexes (>3-fold longer than DTG: BIC, 2.5 hours; DTG, 0.65 hours; $P=0.0076$).²

References

1. Hightower KE, Wang R, Deanda F, et al. Dolutegravir (S/GSK1349572) exhibits significantly slower dissociation than raltegravir and elvitegravir from wild-type and integrase inhibitor-resistant HIV-1 integrase-DNA complexes. *Antimicrob Agents Chemother*. 2011;55(10):4552-4559. <http://www.ncbi.nlm.nih.gov/pubmed/21807982>
2. White K, Niedziela-Majka A, Novikov N, et al. Bictegravir Dissociation Half-life from HIV-1 G140S/Q148H Integrase-DNA Complexes [Poster 497]. Paper presented at: Conference on Retroviruses and Opportunistic Infections (CROI); 13-16 February, 2017; Seattle, Washington.

Abbreviations

BIC=bictegravir
DTG=dolutegravir
EVG=elvitegravir

FTC=emtricitabine
INSTI=integrase strand
transfer inhibitor interferon

RAL=raltegravir
TAF=tenofovir alafenamide

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Biktarvy US Prescribing Information available at:

www.gilead.com/-/media/files/pdfs/medicines/hiv/biktarvy/biktarvy_pi.

Follow-Up

For any additional questions, please contact Gilead Medical Information at:

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