

# Rilpivirine-Tenofovir DF-Emtricitabine (*Complera*)

## Table of Contents

- [Rilpivirine-Tenofovir DF-Emtricitabine \*Complera\* Editor's Summary](#)
- [Drug Summary](#)
- [Key Clinical Trials](#)
- [Adverse Effects](#)
- [Use In Pregnancy](#)
- [Resistance](#)
- [Key Drug Interactions](#)

## Drug Summary

Rilpivirine-tenofovir disoproxil fumarate (DF)-emtricitabine is a single-tablet regimen option for certain treatment-naïve individuals. This single-tablet regimen is generally well tolerated, but several important factors limit its use. Notably, rilpivirine-tenofovir DF-emtricitabine should not be offered to individuals with HIV RNA level above 100,000 copies/mL or CD4 count below 200 cells/mm<sup>3</sup> due to inferior virologic response rates. In addition, it must be taken with a meal and it is contraindicated for individuals who are taking a proton pump inhibitor. A similar option with a different tenofovir component (rilpivirine-tenofovir alafenamide-emtricitabine) is also available and may be preferable because of potential for reduced risk of renal adverse events and bone toxicity.

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## Key Clinical Trials

Rilpivirine-tenofovir DF-emtricitabine was compared with efavirenz-tenofovir DF-emtricitabine and demonstrated similar virologic efficacy overall, except that more virologic failures occurred in the rilpivirine arm in the subset of participants with baseline HIV RNA greater than 100,000 copies/mL or baseline CD4 count less than 200 cells/mm<sup>3</sup> or less than 95% adherence [[ECHO](#)]. A subsequent study showed similar virologic efficacy with these two regimens, even in patients with baseline HIV RNA greater than 100,000 copies/mL, but more treatment-emergent resistance occurred in the rilpivirine arm, particularly in subjects with a baseline HIV RNA above 100,000 copies/mL [[STaR](#)]. Participants in both studies tolerated rilpivirine better than efavirenz. Among individuals who developed virologic failure, rates of NNRTI resistance, NNRTI cross-resistance, and accompanying NRTI resistance were higher with rilpivirine-based therapy than efavirenz-based therapy. Several studies of switching to the fixed dose regimen of rilpivirine-tenofovir DF-emtricitabine from other antiretroviral regimens in patients with well-controlled HIV and no resistance to components of the study drugs have shown excellent safety and virologic control, including switches from efavirenz-tenofovir DF-emtricitabine [[GS-264-0111](#)] and from two NRTIs plus ritonavir-boosted protease inhibitor [[SPIRIT](#)].

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## Adverse Effects

Rilpivirine-tenofovir DF-emtricitabine is generally well tolerated. Side effects can include headache, insomnia, depression, rash, or elevation of hepatic transaminases. Supratherapeutic doses of rilpivirine can cause QT prolongation; therefore, caution should be used when prescribing rilpivirine-containing therapy with other QT prolonging agents or medications that may significantly increase levels of rilpivirine; if rilpivirine must be used in either these situations, QT should be monitored.

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## Use In Pregnancy

In the HHS Perinatal Guidelines section Recommendations for Use of Antiretroviral Drugs During Pregnancy (last updated October 19, 2017), **rilpivirine-tenofovir DF-emtricitabine** is listed as an Alternative NNRTI Regimen in the category of Alternative Initial Regimen in Pregnancy. Note that rilpivirine-tenofovir DF-emtricitabine is not recommended for pregnant women with a pretreatment HIV RNA level greater than 100,000 copies/mL or CD4 cell count below 200 cells/mm<sup>3</sup>, or with concomitant proton pump inhibitor use. There are some rilpivirine pharmacokinetic data available in pregnancy but relatively little experience with use of the single-table regimen rilpivirine-tenofovir DF-emtricitabine in pregnancy.

- For additional information regarding the safety and toxicity of rilpivirine-tenofovir DF-emtricitabine in pregnancy see the HHS Perinatal Guidelines summaries on [Rilpivirine](#), [Tenofovir DF](#), and [Emtricitabine](#).
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## Resistance

For a listing of the most common clinically significant mutations associated with rilpivirine (RPV) resistance, see the [NNRTI Resistance Notes on the Stanford University HIV Drug Resistance Database](#).

For a listing of the most common clinically significant mutations associated with tenofovir DF (TDF) and/or emtricitabine (FTC) resistance, see the [NRTI Resistance Notes on the Stanford University HIV Drug Resistance Database](#).

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## Key Drug Interactions

For complete information on rilpivirine-tenofovir df-emtricitabine-related drug interactions, see the [Drug Interactions section in the Rilpivirine-Tenofovir DF-Emtricitabine \(Complera\) Prescribing Information](#).

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