

Rilpivirine-Tenofovir alafenamide-Emtricitabine (Odefsey)

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Drug Summary

Rilpivirine-tenofovir alafenamide-emtricitabine is a single-tablet regimen option for treatment-naïve individuals. This single-tablet regimen is generally well tolerated, but several important factors limit its use. Rilpivirine-tenofovir alafenamide-emtricitabine should not be offered to individuals with a pretreatment HIV RNA level above 100,000 copies/mL or pretreatment CD4 count less than 200 cells/mm³ because virologic response rates are lower in these patients. In addition, it is contraindicated for individuals who are taking a proton pump inhibitor and it must be taken with a meal. It is approved for use in the setting of stable mild to moderate renal insufficiency (creatinine clearance as low as 30 mL/min). A similar option with a different tenofovir component (rilpivirine-tenofovir DF-emtricitabine) is also available.

Guidelines for use in Antiretroviral-Naïve Patients

In the July 14, 2016 version of the HHS Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents, **rilpivirine-tenofovir alafenamide-emtricitabine** is designated as listed below for treatment-naïve patients:

RECOMMENDED Regimen Options

- None

ALTERNATIVE Regimen Options

- **Rilpivirine-tenofovir alafenamide-emtricitabine (BII)** - only if HIV RNA less than 100,000 copies/mL and CD4 count above 200 cells/mm³

Key Clinical Trials

Randomized clinical trials evaluating the combination tablet rilpivirine-tenofovir alafenamide-emtricitabine have not yet been published. The FDA approval of rilpivirine-tenofovir alafenamide-emtricitabine was based on extrapolation from prior studies that used rilpivirine-tenofovir DF-emtricitabine or tenofovir alafenamide-based regimens. The rilpivirine-tenofovir DF-emtricitabine studies included (1) pooled data in the ECHO and THRIVE studies involving 550 treatment-naïve patients and (2) data from 317 carefully selected patients with virologic control who switched from a virologically suppressive PI-based regimen to rilpivirine-tenofovir DF-emtricitabine [[SPIRIT \(GS-264-0106\)](#)]. The tenofovir alafenamide-related studies showed excellent virologic and safety data from (1) treatment-naïve patients who received elvitegravir-cobicistat-tenofovir alafenamide-emtricitabine [[GS-292-0104/GS-292-0111 \(Study 104/111\)](#)], (2) patients who were virologically-suppressed on a tenofovir-DF-based regimen with no significant antiretroviral resistance mutations and who switched to elvitegravir-cobicistat-tenofovir alafenamide-emtricitabine [[GS-292-0109 \(Study 109\)](#)], and (3) virologically-suppressed patients with a creatinine clearance of 30 to 69 mL/min who switched to elvitegravir-tenofovir alafenamide-emtricitabine [[GS-292-0112 \(Study 112\)](#)]. Clinical trials assessing a switch to fixed-dose combination rilpivirine-tenofovir alafenamide-emtricitabine from either fixed-dose combination efavirenz-tenofovir DF-emtricitabine [[GS-366-1160 \(Study 1160\)](#)] or fixed-dose rilpivirine-tenofovir DF-emtricitabine [[GS-366-1216 \(Study 1216\)](#)] in patients with virologic suppression are ongoing.

Adverse Effects

Rilpivirine-tenofovir alafenamide-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 with other QT prolonging agents or other medications that may significantly increase levels of rilpivirine; if rilpivirine must be used in either of these situations, QT should be monitored.

Use In Pregnancy

In the October 26, 2016 version of the HHS Perinatal Guidelines, **rilpivirine-tenofovir alafenamide-emtricitabine** is designated in the category of Insufficient Data in Pregnancy to Recommend Routine Use in Initial Regimens for Antiretroviral-Naïve Women.

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

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 alafenamide (TAF) and/or emtricitabine (FTC) resistance, see the [NRTI Resistance Notes on the Stanford University HIV Drug Resistance Database](#). Note that both tenofovir alafenamide and tenofovir disoproxil fumarate are converted to tenofovir disphosphate, the active form of the drug. Thus, resistance mutations for tenofovir alafenamide (TAF) and tenofovir disoproxil fumarate (TDF) are the same.

Key Drug Interactions

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

No Clinical Trials Available

We do not currently have any clinical trials on file for this drug.