# Odefsey

**Generic Name:** rilpivirine + emtricitabine + tenofovir alafenamide

**Pronunciation:** oh-DEF-see

**Abbreviation:** R + FTC + TAF

**Drug Class:** Complete Regimens

**Company:** Gilead Sciences and Janssen Therapeutics

**Approval Status:** Approved

**Generic Version Available:** No

## Drug Indication

An alternative treatment regimen for antiretroviral-naive people living with HIV (with viral loads below 100,000 copies and CD4 cell counts above 200), as indicated by the U.S. Department of Health and Human Services (DHHS) Panel on Antiretroviral Guidelines for Adults and Adolescents. Visit https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/ for the full DHHS guidelines for adults and adolescents.

## General Info

Odefsey is a single-tablet regimen HIV medication. It contains one non-nucleoside reverse transcriptase inhibitor (NNRTI) and two nucleoside reverse transcriptase inhibitors (NRTIs). Odefsey was approved by the U.S. Food and Drug Administration in March 2016, for use by people living with HIV who are 12 years of age or older and who are either:

- starting HIV treatment for the first time and have a pre-treatment viral load of no more than 100,000 copies (Odefsy may be less effective than other single-tablet regimens for those with higher viral loads at the time therapy is started);
- or those wishing to switch their current regimens (provided that they have been on a stable regimen for at least six months, have an undetectable viral load and no history of HIV treatment failure or resistance to any of the drugs in Odefsey.)

Odefsey is a combination of three drugs: Edurant (rilpivirine) and Emtriva (emtricitabine) and

tenofovir alafenamide, or TAF. TAF is similar to tenofovir disoproxil fumarate (TDF), the active ingredient in Viread and a component of Stribild, Atripla, Complera and Truvada. TAF, however, can be used at much lower doses and is expected to cause fewer kidney- and bone-related side effects. TAF is currently unavailable as a standalone drug.

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## Dosage

**Adult Dose:** One tablet once a day. Each tablet contains 25 mg rilpivirine + 200mg emtricitabine + 25mg tenofovir alafenamide fumarate.

**Pediatric Dose:** N/A

**Dosing Info:** This is a complete one-pill, once-daily drug regimen. Take with a meal.

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## Side Effects

Possible side effects include trouble sleeping (insomnia), headache and nausea.

Odefsey may lead to new or worsening kidney problems, though this risk is lower compared with those using Complera. Your healthcare provider may do blood tests to check your kidneys before and during treatment with Odefsey.

Odefsey may lead to bone problems, though this risk is lower compared with those using Complera. Problems include bone pain or bones getting soft or thin, which may lead to fractures. Your healthcare provider may do tests to check your bones.

If you also have hepatitis B virus (HBV) and take Odefsey, your hepatitis may become worse if you stop taking Odefsey. Do not stop taking Odefsey without first talking to your healthcare provider.

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## Drug Interactions

The following medications should not be taken while you are being treated with Odefsy:
**Corticosteroids:** dexamethasone (more than a single dose)
**Acid reflux/heartburn medications:** Nexium or Vimovo (esomeprazole), Prevacid (lansoprazole), Prilosec or Zegerid (omeprazole), Protonix (pantoprazole), Aciphex (rabeprazole), or Dexilant (dexlansoprazole)
**Antibiotics:** Mycobutin (rifabutin), Rifamate (rifampin), Priftin (rifapentine)
**Anti-seizure medications:** Tegretol (carbamazepine), Trileptal (oxcarbazepine), Luminal (phenobarbital), Dilantin (phenytoin)

**Herbal products:** St. John’s wort (or products containing St. John’s wort
**Antivirals:** Hepsera (adefovir)

Odefsey should not be combined with any HIV medications that contain any of the active ingredients in Odefsey. These include: Atripla, Complera, Descovy, Edurant (unless recommended by your health care provider and you are taking rifabutin), Emtriva, Genvoya, Stribild, or Viread. Combining Odefesey with HIV medications containing active ingredients similar to those in Odefsey should also be avoided. These include: Combivir, Epivir, Epzicom, Rescriptor, Sustiva, Triumeq, Trizivir, and Viramune.

Odefsey should not be taken at the same time as common antacids, particularly those containing aluminum, magenesium hydroxide, or calcium carbonate; they should be taken at least two hours before or after Odefsey. Acid-block H2-receptor antagonists, such as Tagemet (cimetidine, Pepcid (famotidine), Axid (nizatidine), or Zantac (ranitidine), should be take at least 12 hours before or at least 4 hours after taking Odefsey.

Caution is also necessary when combining Odefsey with Biaxin (clarithromycin), erythromycin, Diflucan (fluconazole), Sporanox (itraconazole), Nizoral (ketoconazole), methadone, Noxafil (posaconazole), Ketek (telithromycin), Vfend (voriconazole). Consult the Odefsey package insert for details regarding these and other possible drug interactions:

http://www.gilead.com/~/media/files/pdfs/medicines/hiv/odefsey/odefsey_patient_pi.pdf?la=en

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## Other Info

Before taking this medication, tell your doctor if you have kidney disease or liver disease (including hepatitis B). In addition, tell your doctor if you are pregnant or planning to become pregnant; if you are breast feeding, and all your medical conditions, including all prescription and over-the-counter medications and supplements you are taking.

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For More Info:
http://www.gilead.com/~/media/files/pdfs/medicines/hiv/odefsey/odefsey_patient_pi.pdf?la=en

Co-Pay Program Info: https://www.poz.com/basics/hiv-basics/drug-assistance-programs

Patient Assistance Program Info:
https://www.poz.com/basics/hiv-basics/drug-assistance-programs

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